Unpublished Cases

AFSCME v. Ortho-Mcneil-Janssen Pharms., Inc.

United States District Court for the Eastern District of Pennsylvania

March 11, 2010, Decided; March 11, 2010, Filed

CIVIL ACTION No. 08-cv-5904

Reporter
2010 U.S. Dist. LEXIS 23181 *; 2010 WL 891150

AMERICAN FEDERATION OF STATE COUNTY AND MUNICIPAL EMPLOYEES, DISTRICT COUNCIL 47 HEALTH AND WELFARE FUND, et al., Plaintiffs, v. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., et al., Defendants.

Subsequent History: Motion granted by, in part, Motion denied by, in part *Am. Fedn. of State County & Mun. Emples. v. Ortho-Mcneil-Janssen Pharms., Inc., 2010 U.S. Dist. LEXIS 135371 (E.D. Pa., Dec. 21, 2010)*

Core Terms

patches, fentanyl, Defendants', buyer, notification, unjust enrichment, notice, notify, third-party, allegations, seller, unfair, pled, motion to dismiss, requirements, patients, payors, screws, manufacturer, household, purchases, consumer, warranty, mcg, tobacco company, deceptive acts, injury-in-fact, recalled, damages, gel

Counsel: **[*1]** For AMERICAN FEDERATION OF STATE, COUNTY AND MUNICIPAL EMPLOYEES, DISTRICT COUNCIL 47 HEALTH AND WELFARE FUND, PHILADELPHIA FIREFIGHTERS UNION LOCAL NO. 22 HEALTH AND WELFARE FUND, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED, Plaintiffs: WILLIAM D. MARVIN, LEAD ATTORNEY, COHEN PLACITELLA & ROTH TWO COMMERCE SQUARE, PHILADELPHIA, PA.

For ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., SANDOZ, INC., ALZA CORPORATION, Defendants: KATHRYN E. DEAL, LEAD ATTORNEY, DAVID J. ANTCZAK, EDWARD M. POSNER, DRINKER BIDDLE & REATH LLP, PHILADELPHIA, PA.

Judges: CYNTHIA M. RUFE, UNITED STATES DISTRICT JUDGE.

Opinion by: CYNTHIA M. RUFE

Opinion

MEMORANDUM OPINION AND ORDER

RUFE, J.

Plaintiff American Federation of State, County and Municipal Employees, District Council 47 Health and Welfare Funds, and Philadelphia Firefighters Union Local No. 22 Health and Welfare Fund bring this action against Defendants Ortho-McNeil-Jannsen Pharmaceuticals, Inc. ("OMJ"), Sandoz, Inc., and ALZA Corporation ("ALZA"), alleging violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), breach of express and implied warranties, and unjust enrichment. Before the Court is Defendants' Motion to Dismiss Plaintiffs' **[*2]** Complaint. [1] For the reasons set forth below, the Motion will be granted in part and denied in part.

I. FACTUAL AND PROCEDURAL BACKGROUND

Defendants OMJ and Sandoz, Inc. market and distribute the fentanyl transdermal system patch ("fentanyl patch"), which is a Schedule II narcotic, available only through a doctor's prescription, designed to deliver a steady, controlled dosage of a powerful medication that provides relief for severe and chronic pain. [2] ALZA, an affiliate of OMJ, contracted with OMJ and Sandoz to manufacture and supply fentanyl patches throughout the United States. [3] OMJ distributes the patches under the brand name Duragesic and Sandoz distributes the

[1] Document No. 14.

[2] Compl. [Document No. 1] PP 6-7, 16.

[3] Id. P 8.

patches under a generic equivalent. [4] The fentanyl patches are available in a variety of dosage delivery rates (e.g., 12.5, 25, 50, 75 and 100 micrograms per hour ("mcg/hour")). [5]

On February 12, 2008, OMJ announced a recall of all 25 mcg/hour Duragesic patches (and its generic equivalent) stamped with expiration dates on or before December 2009. [6] The official press release stated, in pertinent part, that:

> [The 25mcg/hr fentanyl transdermal system patches] **[*3]** being recalled may have a cut along one side of the drug reservoir within the patch. The result is possible release of fentanyl gel from the gel reservoir into the pouch in which the patch is packaged, exposing patients or caregivers directly to fentanyl gel. Fentanyl patches that are cut or damaged in any way should not be used. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal….Anyone who has 25 mcg/hr…fentanyl patches should check the box or foil pouch for the expiration date… The recalled patches all have expiration dates on or before December 2009. The cut edge in affected patches can be seen upon opening the sealed foil pouch that holds the patch. Affected patches should not be handled directly. [7]

Plaintiffs are health and welfare trust funds that provide medical coverage, including prescription drug coverage, to their members and their members' dependents. [8] Plaintiffs and other similarly situated third-party payors have paid for supplies of 25 mcg/hour fentanyl patches, which were later recalled by Defendants, on behalf of their **[*4]** qualified members. [9] As a result of the recall, Plaintiffs allege that they, and similarly situated third-party payors, paid or will pay expenses related to the purchase and reimbursement of 25 mcg/hour fentanyl patches that had to be discarded. [10]

On December 19, 2008, Plaintiffs filed the underlying class-action Complaint, alleging the following: COUNT I: Violations of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL"); COUNT II: Breach of an Express Warranty under the Pennsylvania Uniform Commercial Code ("UCC"); COUNT III: Breach of an Implied Warranty; and COUNT IV: Rescission / Unjust Enrichment. On March 25, 2009, Defendants filed the instant Motion to Dismiss, asserting several grounds for dismissal of Plaintiffs' Complaint under *Federal Rules of Civil Procedure 12(b)(1)* and *12(b)(6)*. The Court has carefully reviewed Defendants' Motion, Plaintiffs' Response, [11] Defendants' Reply, [12] and all accompanying materials, and this matter is now ready for disposition.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(1) allows a party to move for dismissal of any claim wherein the district **[*5]** court lacks subject matter jurisdiction. [13] When considering a 12(b)(1) motion, the court "review[s] only whether the allegations on the face of the complaint, taken as true, allege sufficient facts to invoke the jurisdiction of the district court." [14] When subject matter jurisdiction is challenged under *12(b)(1)*, the plaintiff must bear the burden of persuasion. [15]

In order for a plaintiff to have standing in federal court, the case or controversy presented by the plaintiff must be justiciable and establish an injury-in-fact. [16] To establish an injury-in-fact, a plaintiff must allege that: (1) defendant violated a legally protected interest that is concrete and particularized, and actual or imminent -- not merely an injury that is "conjectural" or "hypothetical," (2) the injury is fairly traceable to the challenged conduct, and (3) the injury is redressable by

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[4] Id.

[5] Id.

[6] Id. P 19.

[7] Defs.'Mot. to Dismiss, Ex. A; see also Compl. P 20.

[8] Compl.PP 1-2.

[9] Id. P 21.

[10] Id. P 23.

[11] Document No. 15.

[12] Document No. 19.

[13] *FED. R. CIV. P. 12(b)(1)* (West 2009 Revised).

[14] *Licata v. U.S. Postal Serv., 33 F.3d 259, 260 (3d Cir. 1994)*.

[15] *Kehr Packages v. Fidelcor, Inc., 926 F.2d 1406, 1409 (3d Cir. 1991)*.

[16] See *Flast v. Cohen, 392 U.S. 83, 95, 88 S. Ct. 1942, 20 L. Ed. 2d 947 (1968)*.

a remedy that federal courts are permitted to give. [17] If the complaint fails to satisfy these requirements, "a federal court does not have subject **[*6]** matter jurisdiction…[and] the claim[s] must be dismissed." [18]

Federal Rule of Civil Procedure 12(b)(6) allows a party to move for dismissal for failure to state a claim upon which relief can be granted. [19] Under *12(b)(6)*, the moving party "bears the burden of showing no claim has been stated." [20] The court must "accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, and view them in a light most favorable to the non-moving party." [21] The United States Supreme Court clarified this standard in Bell Atlantic Corporation v. Twombly, explaining that "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." [22] Instead, a plaintiff must allege facts that "raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." [23]

III. DISCUSSION

A. FRCP 12(b)(1)

Relying upon *FRCP12(b)(1)*, Defendants assert that the Court lacks subject matter jurisdiction because Plaintiffs allegedly (1) failed to plead an injury-in-fact sufficient to satisfy Article III standing; (2) lack standing as a "person" under the UTPCPL; and (3) do not fall within the class of buyers or end-users that may recover for a breach of warranty under the Pennsylvania UCC. The Court will address each argument separately below.

(i) Injury-In-Fact

Defendants argue that Plaintiffs' Complaint failed to allege that any of their members actually purchased defective fentanyl patches. Defendants assert that unless Plaintiffs pled that their members received patches that were actually defective, Plaintiffs' alleged injury is merely conjectural and hypothetical. Defendants further assert that "[p]ayment for **[*8]** a product that is recalled as a precautionary measure because it might have a defect is not the legal equivalent of payment for a product that actually is defective." [24] In effect, Defendants' arguments attempt to distinguish between patches that were actually defective (*e.g.*, patches that contained a cut on the gel reservoir) and patches that were subject to Defendants' product recall. The Court finds, however, that Defendants' recall notice made no such distinction. The recall notice warned that "[f]entanyl patches that are cut or damaged in any way should not be used," and that "[e]xposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal." [25] Plaintiffs pled that as a result of this warning and product recall, they "have paid or will pay expenses related to the purchase of and reimbursement for supplies of 25 mcg/hour fentanyl patches [previously purchased for their members, bearing the relevant expiration dates] that were unusable, worthless, and had to be discarded." [26] These facts, if accepted as true, plead an economic loss that is concrete, particular, and traceable to a defect resulting from Defendants' **[*9]** manufacturing and distribution process, and would permit a remedy if Plaintiffs are successful on the merits.

Additionally, Plaintiffs' claim, as pled, seeks monetary damages for the purchase price of the recalled fentanyl patches, an injury that directly impacts Plaintiffs, not just the consequential damages that their members may incur from exposure to the defective patches. [27] Claims for monetary damages generally satisfy the injury-in-fact

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[17] See *Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992)*.

[18] *Taliaferro v. Darby Twp. Zoning Bd., 458 F.3d 181, 188 (3d Cir. 2006)*.

[19] *FED. R. CIV. P. 12(b)(6)* **[*7]** (West 2009 Revised).

[20] *Kehr Packages, 926 F.2d at 1409*.

[21] *Rocks v. City of Philadelphia, 868 F.2d 644, 645 (3d Cir. 1989)*.

[22] *550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)* (citations omitted).

[23] Id. (citations omitted).

[24] Defs.' Mot. at 8.

[25] Defs.'Mot., Ex. A; see also Compl. P 20.

[26] Compl. PP 21, 23.

[27] Compl. at 13-14; see also Pls.' Answer to Defs.' Mot. to Dismiss at 5.

threshold. [28] Based on the allegations pled in the Complaint, the Court finds that Plaintiffs have satisfied the injury-in-fact requirements necessary to establish Article III standing.

(ii) Standing Under the UTPCPL

Defendants argue, in the alternative, that Plaintiffs are not "persons" under the UTPCPL, and therefore do not have standing to sue, because "[t]hey do not themselves obtain or consume the fentanyl patches in question" nor were their purchases made for primarily "personal, family, or household purposes." [29] Pennsylvania **[*10]** courts, however, have long recognized the ability of third-party trusts and associations to assert UTPCPL claims on behalf of their constituent members based on the statute's broad definition of "person." [30] *Section 201-9.2(a)* of the UTPCPL permits a private action for the recovery of damages for "[a]ny person who purchases or leases goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money . . . as a result of . . . [any] act or practice declared unlawful by this act . . . ." [31] The UTPCPL defines "person" as "natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations, and any other legal entities." [32] In addition, the "purpose" requirement of *§ 201-9.2(a)* focuses on whether the final consumer uses the product for personal, family or household use, not whether the third-party entity personally uses the product or merely purchases it. [33]

Defendants, nonetheless, rely on Balderston v. Medtronic Sofamor Danek, Inc. to support their position. [34] In Balderston, the plaintiff-physician filed suit against a manufacturer of surgical screws, which were used on his patients during spinal fusion operations, claiming that the defendant misrepresented the FDA's approval status of the screws. The plaintiff claimed that he had been misled as to the FDA's approval status, and was subsequently exposed to lawsuits. The district court, however, determined that the plaintiff's patients, not the plaintiff, had actually purchased the screws and therefore concluded that the plaintiff lacked standing. The district court further concluded that plaintiff could not qualify **[*12]** as a purchaser because any purchase he would have made was for business purposes, not for "personal, family, or household" use. [35] On appeal, the Third Circuit affirmed the district court's findings and noted that plaintiff unequivocally acknowledged that "purchase [of the surgical screw was] by the consumer, the patient…[and that] neither plaintiff nor his practice [were] ever billed for the screw and [did] not pay for it." [36]

The distinctions between the facts in *Balderston* and the facts as pled before this Court are clear. Whereas in Balderston, the plaintiff could in no way be considered a purchaser or even consumer of the goods at issue, Plaintiffs here actually paid for the fentanyl patches *on behalf* of their members for their **[*13]** members' personal, family or household use. [37] This places Plaintiffs in a far different relationship with Defendants that the distant or tangential relationship between the plaintiff and the defendant in Balderston. The facts here compel the conclusion that Plaintiffs allegations, as pled in the Complaint, strongly support the position that they

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[28] See *Danvers Motor Co. v. Ford Motor Co., 432 F.3d 286, 293 (3d Cir. 2005)*.

[29] Defs.' Mot. at 10-11.

[30] See *Commonwealth v. TAP Pharmaceutical Products, Inc., 885 A.2d 1127, 1142-1143 (Pa. Commw. 2005)* (definition of "person" under *§ 9.2(a)* includes third-party medical benefit payors); See also *Valley Forge Towers South Condominium v. Ron-Ike Foam Insulators, Inc., 393 Pa. Super. 339, 574 A.2d 641, 644-645 (Pa. Super. 1990)* **[*11]** ("associations" were explicitly included within the definition of "person" under *§ 201-2(2)* and that even though the breach of warranty claim for defective roofing membranes affected the individual unit owners the association represented, the condominium association could assert a claim as a "person" under *§ 9.2(a)*).

[31] *73 PA. STAT. § 201-9.2(a)* (2010 Electronic Update).

[32] Id. *§ 201-2(2)*.

[33] See *TAP Pharm. Prods., 885 A.2d at 1142-1143*; See also *Valley Forge Towers, 574 A.2d at 649*.

[34] *285 F.3d 238 (3d Cir. 2002)* (a surgeon filed a UTPCPL claim against the manufacturer of pedicle screws, which were used on his patients during various surgical procedures. The Third Circuit held the surgeon did not qualify as a "person" under the UTPCPL because his patients actually purchased the screws, and even if he had directly purchased the screws, the court reasoned that he purchased them primarily for business purposes).

[35] *Id. at 240*.

[36] *Id. at 241*.

[37] See Compl. PP 26, 35.

have standing as purchasers under the UTPCPL. The Court finds that since Plaintiffs purchased the fentanyl patches on behalf of their members in their representative capacity, and those patches were purchased for the personal, family and household use of their members, Plaintiffs have properly asserted a claim under the UTPCPL. [38]

(iii) Buyers Under Pennsylvania's UCC

As a third alternative argument for dismissal under *FRCP 12(b)(1)*, Defendants assert that because "plaintiffs merely pay or reimburse some or all of the purchase price of the covered prescription medicines that their members buy and use," Plaintiffs, as third-party payors, do not qualify **[*14]** as "buyers" under Pennsylvania's UCC. [39] Defendants' argument, however, essentially takes a section of the UCC that *extends* warranty protections to relatives and persons in the same household as the buyer, and incorrectly suggests to this section somehow *limits* buyers to only a "natural persons."

Section 2103(a) of the UCC defines "buyer" as a "person who buys or contracts to buy goods." [40] *Section 1201(b)(27)* of the UCC defines "person" as "[a]ny individual; corporation; business trust; estate; trust; partnership; limited liability company; association; joint venture; government; governmental subdivision, agency or instrumentality, public corporation or other legal or commercial entity." [41] Contrary to Defendants' arguments, the definition of "person" under the UCC is not limited to a "natural person;" rather, the UCC uses a very broad definition, which includes corporations, trusts and business trusts. Therefore, the Court finds that Plaintiffs are in fact considered both "persons" and "buyers" under the UCC. Accordingly, each of Defendants' arguments offered to support its motion to dismiss the Complaint for a lack of subject matter jurisdiction are denied.

B. FRCP 12(b)(6)

Relying upon *FRCP12(b)(6)*, Defendants assert that the Court should dismiss Plaintiffs' Complaint because Plaintiffs failed to state a claim for which relief can be granted by not pleading that: (1) Defendants committed unfair or deceptive acts or practices under the UTPCPL; (2) Plaintiffs provided Defendants reasonable notification of the alleged breach of warranty as required by *Title 13 of the Pennsylvania Consolidated Statutes, Section 2607(c)(1)*; (3) a warranty was actually breached; (4) an express warranty extended to them as third-party medical benefit payors; and (5) Defendants actually received a benefit as required for a claim of unjust enrichment. The Court will address each argument separately below.

(i) The UTPCPL

Defendants argue that Plaintiffs' UTPCPL claims should be dismissed for failure to state a claim upon which relief can be granted because Plaintiffs failed to: (1) identify, with particularity, a false or deceptive representation made by Defendants that was material to Plaintiffs' coverage decisions and (2) plead justifiable reliance on Defendants' alleged representations. In support of their first point, **[*16]** Defendants assert that in order for Plaintiffs to plead an unfair or deceptive act or practice under the UTPCPL, Plaintiffs must allege that the "defendants made a representation that their patches would invariably be free from defects." [42] The UTPCPL, however, defines unfair or deceptive acts or practices to include representations that "goods . . . have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have," or representations "that goods . . . are of a particular standard, quality, or grade . . . , if they are of another." [43] Under both definitions, Plaintiffs allegations in the complaint, if taken as true, sufficiently plead an unfair or deceptive act committed by Defendants. The "unfair and deceptive" act alleged in Plaintiffs' Complaint is Defendants' representation that the recalled fentanyl patches would release the drug at a safe dosage rate. However, due to the defect and subsequent recall, the fentanyl patches could actually release the drug at a significantly higher and more dangerous dosage rate, which rendered the patches useless to Plaintiffs.

As to their second **[*17]** point, Defendants assert that any alleged reliance by Plaintiffs that the fentanyl patches would be completely free from cuts or damage

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[38] *See TAP Pharm. Products, 885 A.2d at 1142-1143* (distinguishing Balderston from the Commonwealth's third-party payor programs); See also *Valley Forge Towers, 574 A.2d at 649*.

[39] Defs. Mot. at 14-15.

[40] *13 PA. CONS. STAT. § 2103(a)* **[*15]** (2010 Electronic Update).

[41] Id. *§ 1201(b)(27)*.

[42] Defs.' Mot. at 12.

[43] *73 PA. STAT. § 201-2(4)(v)*, *(vii)*.

is not "justifiable," especially given that the fentanyl patches packaging included an insert disclaimer, which warned that broken or cut patches could lead to overdose or death. [44] Plaintiffs argue in opposition that the Complaint sufficiently pleads "the type of representations that fall into the traditional scope of consumer protection statutes -- where a product seller promises one thing but delivers another." [45] Plaintiffs assert in the Complaint that Defendants represented to end-users, physicians and third-party payors that the fentanyl patches were designed to safely release the prescription drug at a rate of 25 mcg/hour. However, because of the manufacturing defect, the patches potentially released the drug at an excessive, possibly fatal, rate. Accordingly, the Court finds that Plaintiffs sufficiently alleged that Defendants committed unfair or deceptive acts or practices under the UTPCPL and Plaintiffs sufficiently pled justifiable reliance on the alleged unfair or deceptive acts in their Complaint.

(ii) [*18] Breach of Implied and Express Warranty Under Pennsylvania UCC

Defendants argue that Plaintiffs' breach of express and implied warranty claims should be dismissed for failure to state a claim upon which relief can be granted because Plaintiffs failed to allege in their Complaint that they notified Defendants of the breach of warranty. Under *§ 2607(c)(1)* of the UCC, a buyer must "within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." [46] Defendants argue that "[t]he purpose of the notice requirement is to afford the seller a reasonable time within which to cure the breach or settle the claim." [47] Plaintiffs argue in opposition that Defendants cannot complain of a lack of notice for the breach of warranty, as it was Defendants themselves who first gave notice to the purchasers that the fentanyl patches were defective through the recall notice. According to Plaintiffs, "Defendants were already well aware of the breach and had an opportunity to make good." [48]

Plaintiffs' argument, however, that notification under *§ 2607(c)* is unnecessary **[*19]** because Defendants had actual or constructive knowledge of the breach, is not supported by the language of the UCC, its statutory purpose, or existing case law interpreting *§ 2607*. Plaintiffs appear to confuse the term "notice" with "notify" -- which the UCC explicitly distinguishes. Under UCC *§ 1202(a)*, a person has *notice* of a fact when the person has actual knowledge of it, has received notification of it, or, from all of the facts and circumstances known to that person at the time in question, has reason to know it exists. [49] On the other hand, *§ 1202(d)* defines *notify* to mean "give a notice or notification to another person by taking such steps as may be reasonably required to inform the other person in ordinary course, whether or not the other person actually comes to know of it." [50]

The purpose of notification under *§ 2607(c)(1)* is not intended to merely make the seller aware of the breach; rather, the notification must "inform[] the seller that the transaction is claimed to involve a breach, and thus opens the way for normal settlement through negotiation." [51] Thus, the purpose of notification under *§ 2607(c)* is to allow the seller **[*20]** an opportunity to resolve the dispute regarding an alleged breach before the buyer initiates a lawsuit. Therefore, even assuming that Defendants were aware that the fentanyl patches were defective, Defendants may not have been aware of Plaintiffs' intent to file a class action lawsuit, and were denied the opportunity to negotiate or settle this claim without judicial involvement. To "notify" under the UCC requires the affirmative act of notification, and *Section 2607(c)(1)* explicitly requires the buyer to "notify the seller of breach or be barred from any remedy." [52] Plaintiffs' "constructive notice" argument does not address whether Plaintiffs ever actually and affirmatively notified Defendants of the breach, as required by *§ 2607(c)(1)*, prior to initiating this litigation.

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[44] Defs.' Mot. at 13.

[45] Pls.' Answer at 11.

[46] *13 PA. CONS. STAT. § 2607(c)(1)*.

[47] Defs.' Mot. at 16.

[48] Pls.' Answer at 14.

[49] *13 PA. CONS. STAT. § 1202(a)*.

[50] Id. *§ 1202(d)*.

[51] Id. *§ 2607 cmt. 4*; see also *Beneficial Comm. Corp. v. Brueck, 23 Pa. D. & C.3d 34, 37 (Pa. Ct. Comm. Pl. 1982)*("*Section 2607(c)*'s requirement that the buyer notify the seller of the breach within a reasonable time after he discovers or should have discovered the breach gives the manufacturer the opportunity to cure the defect, settle the claim through negotiation, and gather information that may assist in defending **[*21]** the claim.").

[52] Id. *§ 2607(c)(1)*.

Additionally, the Third Circuit recently analyzed § 2607(c) of the UCC in Vanalt Electrical Construction, Inc. v. Selco Manufacturing Corporation, and concluded that a "review of Pennsylvania precedent and other authorities interpreting the UCC indicates that the Pennsylvania Supreme Court would agree that a buyer must prove compliance with Section 2607 before recovering for a breach of contract or warranty involving nonconforming goods . . . ." [53] Here, the Court must also treat the § 2607(c) reasonable notification requirement as a condition precedent to recovery, with Plaintiffs bearing the burden to prove that reasonable notification was given. As reasonable notification is a material element necessary to sustain recovery of a UCC breach of warranty claim, Plaintiffs were required to affirmatively allege that they reasonably notified Defendants. [54] Inasmuch as § 2607(c) bars a buyer's recovery absent the buyer providing reasonable notification of the breach, it follows that a buyer must also plead, at a minimum, in its Complaint, that it provided reasonable notification in order to state a viable claim for recovery. [55] Plaintiffs were not required **[*22]** to allege in the Complaint that the notification occurred in any substantial form (such as a letter or a formal demand), as the "reasonableness" of the notice is a factual matter left for the jury to resolve. However, Plaintiffs needed to allege, at a minimum, that they notified Defendants in some manner "or be barred from any remedy." [56] The Court finds that Plaintiffs failed to allege that they provided Defendants with notification as required by § 2607(c)(1) of the UCC. As such, the Court further finds that Plaintiffs' breach of express and implied warranty claims should be dismissed under FRCP 12(b)(6).

(iii) Unjust Enrichment

Defendants also argue that Plaintiffs' unjust enrichment claim should be dismissed for failure to state a claim upon which relief can be granted. To satisfy the pleading requirements of unjust enrichment, the plaintiff must allege the following elements in its complaint: (1) a benefit conferred upon one party by another, (2) appreciation of the benefit by the recipient, and (3) acceptance and retention of the benefit under circumstances that would make it inequitable or unjust for the recipient to retain the benefit without payment of value. [57]

Defendants offer two distinct arguments to defeat Plaintiffs' unjust enrichment claim. First Defendants assert that when an unjust enrichment claim is based upon tortious conduct, and the court dismisses the tort claims based upon the same **[*24]** conduct, the court must also dismiss the unjust enrichment claim as it "is essentially another way of stating a traditional tort claim." [58] The Court finds, however, that this argument is inconsequential and cannot constitute a basis for dismissal in this instance because the Court does not dismiss Plaintiffs' UTPCPL claim.

Second, Defendants assert that Plaintiffs, as third-party payors obligated to reimburse their members' prescription drug expenses, did not confer a "benefit" to Defendants in any way recognized under the law and that "any 'benefit' inured to [D]efendants was merely 'incidental' to [P]laintiffs' performance of their independent contractual obligations." [59] To support this argument, Defendants rely on Allegheny General Hospital v. Phillip Morris, Inc. [60] The facts of Allegheny General, however, are distinguishable: Allegheny

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[53] 233 Fed. Appx. 105, 111 (3d Cir. 2007) (held in a dispute over the sale of goods, the buyer must prove compliance with the notice requirement of Section 2607" and that "reasonable notification is a precondition to the buyer's recovery for breach", with the buyer bearing the burden to prove its requirements).

[54] See Vanalt, 233 Fed. Appx. at 111; See also Twombly, 550 U.S. at 562 (quoting Car Carriers v. Ford Motor Co., 745 F.2d 1101, 1106 (7th Cir. 1984) (a complaint '"must contain either direct or inferential allegations respecting all the material elements necessary to sustain recovery **[*23]** under some viable legal theory'").

[55] Section 2607(c)(1) requires the buyer to "within a reasonable time after he discovers or should have discovered any breach notify the seller of the breach or be barred from any recovery." 13 PA. CONS. STAT. § 2607(c)(1).

[56] See Id.; see also Vanalt, 233 Fed. Appx. at 112.

[57] Allegheny Gen. Hosp. v. Phillip Morris, Inc., 228 F. 3d 429, 447 (3d Cir. 2000).

[58] Defs.' Mot. at 19.

[59] Id. at 20.

[60] 228 F. 3d at 434, 446-448. (held a hospital's claim of unjust enrichment filed against certain tobacco companies was based on remote and indirect injuries, consequently the tobacco companies had no legal obligation to pay the non-paying patients' medical expenses, and whatever "incidental benefit" the tobacco companies received was insufficient to establish a claim of unjust enrichment).

General involved a hospital's expenses to treat tobacco-related illnesses caused by the patient's prolonged tobacco use. The hospital and tobacco companies had no preexisting relationship, and the hospital did not directly pay the tobacco companies for any products or services. Under such circumstances, the Third Circuit found **[*25]** that the benefit conferred to the tobacco companies was too incidental or remote to establish a claim of unjust enrichment. [61] Here, however, as pled in the Complaint, Plaintiffs directly paid for or reimbursed the purchase costs of fentanyl patches on behalf their members. The benefit in this case is not remote or incidental; rather, the benefit (the amount paid by Plaintiffs to Defendants for defective fentanyl patches) is direct and measurable.

Plaintiffs' Complaint alleges that Defendants "reaped substantial profits from the sale of defective fentanyl patches," and that "Defendants' profits would have been reduced, but for their wrongful and unlawful conduct." [62] Otherwise stated, Plaintiffs pled that they conferred a monetary benefit to Defendants, that Defendants appreciated **[*26]** the benefit, and that the Defendants retained the benefit under inequitable circumstances. The Court finds that these factual allegations, if taken as true, sufficiently plead a claim of unjust enrichment. Accordingly, Defendants' arguments offered to support its motion to dismiss the Complaint for failure to state a claim upon which relief can be granted are denied as to Plaintiffs' unjust enrichment and UTPCPL claims and granted as to Plaintiffs' breach of express and implied warranty claims.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss Counts II and III for Plaintiffs' failure to plead reasonable notification as required by *13 Pa. Cons. Stat. § 2607(c)* is hereby granted. Defendants' remaining general and specific grounds for dismissal under *FRCP 12(b)(1)* and *12(b)(6)*, particularly as to Counts I and IV, are hereby denied.

An appropriate order follows.

ORDER

AND NOW, this 11 day of March 2010, upon consideration th of Defendants' Motion to Dismiss [docket entry No. 14]; Plaintiffs' Answer to Defendants' Motion to Dismiss [docket entry Nos. 15 and 16]; and Defendants' Reply [docket entry No. 19], and for the reasons set forth in the attached Memorandum **[*27]** Opinion, it is hereby **ORDERED** that Defendants' Motion is **GRANTED IN PART** and **DENIED IN PART**. Defendants' Motion to Dismiss Plaintiffs' **COUNTS I** and **IV** is **DENIED**. Defendants' Motion to Dismiss Plaintiffs' **COUNTS II** and **III** is **GRANTED. Counts II and III** are hereby **DISMISSED**.

It is so **ORDERED**.

BY THE COURT:

/s/ Cynthia M. Rufe

CYNTHIA M. RUFE, J.

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[61] Id.

[62] Compl. P 49.

Dipietro v. Glidewell Labs.

United States District Court for the Middle District of Pennsylvania

November 8, 2011, Decided; November 8, 2011, Filed

CIVIL NO. 1:CV-07-1591

Reporter
2011 U.S. Dist. LEXIS 128964 *; 2011 WL 5403568

ANN DIPIETRO, D.D.S., Plaintiff vs. GLIDEWELL LABORATORIES, Defendant vs. IVOCLAR VIVADENT, INC., Third-Party Defendant

Subsequent History: Summary judgment denied by, Motion denied by, As moot DiPietro v. Glidewell Labs., 2011 U.S. Dist. LEXIS 130053 (M.D. Pa., Nov. 9, 2011)

Summary judgment denied by, Motion denied by, in part, As moot DiPietro v. Glidewell Labs., 2012 U.S. Dist. LEXIS 11636 (M.D. Pa., Jan. 31, 2012)

Related proceeding at Dipietro v. Glidewell Labs., 2015 Pa. Super. Unpub. LEXIS 3051 (2015)

Core Terms

summary judgment, tort claim, parties, defense motion, repair, economic loss, unconscionable, gist, breach of contract claim, statute of limitations, limits of liability, damages, replace, economic loss doctrine, warranty, counts, duties

Counsel: **[*1]** For Ann DiPietro, D.D.S, Plaintiff: Robert J. Sugarman, LEAD ATTORNEY, Sugarman & Associates, Philadelphia, PA; Charles R. Pedri, Pedri Law Office, Hazleton, PA.

For Glidwell Laboratories, Defendant: Richard K. Hodges, LEAD ATTORNEY, O'Malley, Harris, Durkin & Perry, P.C., Scranton, PA.

For Ivoclar Vivadent, Inc., Third Party Defendant: George T. Reynolds, Powell, Trachtman, Logan, Carrie & Lombardo, PC, King of Prussia, PA.

For Glidwell Laboratories, Third Party Plaintiff: Richard K. Hodges, LEAD ATTORNEY, O'Malley, Harris, Durkin & Perry, P.C., Scranton, PA.

Judges: William W. Caldwell, United States District Judge.

Opinion by: William W. Caldwell

Opinion

MEMORANDUM

I. Introduction

We are considering a motion for summary judgment filed by Defendant, Glidewell Laboratories. This matter involves Defendant's allegedly defective manufacturing of dental crowns, which were sold to Plaintiff, a dentist. We will examine the motion under the well-established standard. Lawrence v. City of Philadelphia, 527 F.3d 299, 310 (3d. Cir. 2008).

II. Background

Plaintiff is a dentist with a practice in Plymouth, PA. Defendant, Glidewell Laboratories ("Glidewell"), fabricated and manufactured dental crowns and bridges for Plaintiff. Around **[*2]** 2001, Plaintiff began experiencing difficulties with the crowns produced by Glidewell, which Plaintiff attributes to a change in manufacturing materials and processes. These difficulties included discoloration, separation, and flaking of the porcelain surface of crowns. Plaintiff filed the instant suit on February 26, 2007 in the Court of Common Pleas, Luzerne County. On August 29, 2007, the action was removed to the Middle District of Pennsylvania. Plaintiff's complaint included claims under the Restatement of Torts, Second, § 402A, breach of warranty, and negligence. Plaintiff alleges damages of more than $400,000 from repairing the failed product, loss of goodwill, and future time required to replace the defective devices. Glidewell filed a motion for summary judgment on August 5, 2011. Glidewell asserts that Plaintiff's tort claims must be dismissed under the gist of

the action and economic loss doctrines. Additionally, Glidewell seeks summary judgment on statute of limitation grounds and a limitation of liabilities clause.

III. Discussion

A. Tort Claims

Defendant has moved for summary judgment on Plaintiff's tort claims under the doctrines of "gist of the action" **[*3]** and economic loss.

1. The Gist of the Action Doctrine

The gist of the action doctrine "precludes plaintiffs from re-casting ordinary breach of contract claims into tort claims." *eToll Inc., v. Elias/Savion Adver., 2002 Pa. Super. 347, 811 A.2d 10, 14 (Pa. Super. Ct. 2002)*. The doctrine precludes tort claims

> (1) arising solely from a contract between the parties; (2) where the duties allegedly breached were created and grounded in the contract itself; (3) where the liability stems from a contract; or (4) where the tort claim essentially duplicates a breach of contract claim or the success of which is wholly dependent on the terms of a contract.

Id. at 19. "The critical conceptual distinction between a breach of contract claim and a tort claim is that the former arises out of 'breaches of duties imposed by mutual consensus agreements between particular individuals,' while the latter arises out of 'breaches of duties imposed by law as a matter of social policy.'" *Erie Ins. Exch. v. Abbott Furnace Co., 2009 PA Super 88, 972 A.2d 1232, 1238 (Pa. Super. Ct. 2009)* (quoting *Reardon v. Allegheny Coll., 2007 PA Super 160, 926 A.2d 477, 486-87 (Pa. Super. Ct. 2007))*. In determining whether the gist **[*4]** of the action is in tort or contract, the test is "concerned with the nature of the action as a whole." *Id.*

The Defendant's duties to Plaintiff arise from contractual obligations and a violation of these duties is properly brought as a breach of contract claim. *See id. at 1239* (finding defendant's obligation to plaintiff not to design a defective furnace arose from a mutual agreement between parties); *New Hope Books, Inc. v. Datavision Prologix, Inc., 2003 Phila Ct. Com. Pl. LEXIS 62, *13-14 (Phila Ct. Com Pl. 2003)* (holding negligence and strict liability counts are barred by gist of the action and economic loss doctrines where defendant failed to design and produce labels that worked properly). Plaintiff's attempt to bring breach of contract claims under negligence and *section 402A of the Restatement of Torts, Second* cannot stand. We will grant defendant's motion for summary judgment on Plaintiff's tort claims.

2. The Economic Loss Doctrine

Defendant asserts that Plaintiff's tort claims are also barred by the economic loss doctrine. This doctrine, like the gist of the action doctrine, seeks to maintain the barrier between torts and contracts claims. *Werwinski v. Ford Motor Co., 286 F.3d 661, 671 (3d Cir. 2002)*. **[*5]** Tort claims for purely economic loss that flow from a contract are precluded under the economic loss doctrine, because they are properly brought as contract claims. *Id.*

The Pennsylvania Superior Court addressed the effect of the economic loss doctrine on contracts between commercial entities and held "negligence and strict liability theories do not apply in an action between commercial enterprises involving a product that malfunctions where the only resulting damage is to the product itself." *REM Coal Co. v. Clark Equipment, 386 Pa. Super. 401, 563 A.2d 128 (Pa. Super. Ct. 1989)* (adopting Supreme Court's position in *East River Steamship Corp. v. Transamerica Delaval, Inc., 476 U.S. 858, 106 S. Ct. 2295, 90 L. Ed. 2d 865 (1986))*. This position was later adopted for consumer contracts as well. *Jones v. General Motors Corp., 428 Pa Super 544, 631 A.2d 665, 666 (Pa. Super. Ct. 1993)*. The Pennsylvania Supreme Court has stated that "no cause of action exists for negligence that results solely in economic damages unaccompanied by physical injury or property damage." *Excavation Technologies, Inc. v. Columbia Gas Co. of Pa., 604 Pa. 50, 985 A.2d 840, 841 n. 3 (Pa. 2009)*. Interpreting Pennsylvania law, a federal court held "in **[*6]** cases where a product fails to conform and only economic losses result to the product itself and does not cause physical injury or property damage, 'the parties' recovery one against the other for economic losses should be limited to an action on that contract and no additional recovery in negligence or strict liability is permitted.'" *Tennis v. Ford Motor Co., 730 F. Supp. 2d 437 (W.D. Pa. 2010)* (citing *N.Y. State Electric & Gas Corp. v. Westinghouse Electric Corp., 387 Pa. Super. 537, 564 A.2d 919, 926 (Pa. Super. Ct. 1989)*.

In her complaint, Plaintiff brings tort claims based on negligence and *section 402A of the Restatement of Torts, Second*. The only damage Plaintiff alleges is the failure of the crowns provided by Defendant. Plaintiff

does not contend that there was any physical injury or property damage. Recovery for economic loss is properly brought as a breach of contract claim, and under Pennsylvania law the economic loss doctrine precludes recovery under negligence and strict liability claims. Defendant's motion for summary judgment on Plaintiff's negligence and strict liability claims will be granted.

B. Statute of Limitations

The statute of limitations for contract claims **[*7]** in Pennsylvania is set forth in 13 Pa.C.S. § 2725 as follows:

> (a) *General rule.* —An action for breach of any contract for sale must be commenced within four years after the cause of action has accrued. By the original agreement the parties may reduce the period of limitation to not less than one year but may not extend it.
>
> (b) *Accrual of cause of action.* —A cause of action accrues when the breach occurs, regardless of the aggrieved party's lack of knowledge of the breach. A breach of warranty occurs when tender of delivery is made, except that where a warranty explicitly extends to future performance of the goods and discovery of the breach must await the time of such performance the cause of action accrues when the breach is or should have been discovered.

In Pennsylvania, "the statute of limitations will be tolled where 'evidence reveals that repairs were attempted; representations were made that the repairs would cure the defects; and the plaintiff relied upon such representations.'" Hrycay v. Monaco Coach Corp., 2008 U.S. Dist. Lexis 18055, *9 (E.D. Pa 2008) (quoting Keller v. Volkswagen of Am., 1999 PA Super 153, 733 A.2d 642, 646 (Pa. Super. 1999). This is a question of fact. *Id.*

Plaintiff **[*8]** filed her complaint on February 6, 2007. Only seven of the crowns were used within the four-year statute of limitations. Defendant seeks summary judgment on all but these seven instances. Plaintiff asserts that her claim arises under the Magnuson Moss Improvement Warranty Act and that the statute of limitations was tolled due to defendant's misrepresentation that the products would be repaired and replaced. Plaintiff also alleges that there is a seven-year express warranty for repair and replacement of defective devices.

There are genuine issues of material fact regarding defendant's representations to repair or replace defective products. Plaintiff's deposition discusses Defendant's ongoing offer to fix the products. This is a question of fact that may toll the statute of limitations. Defendant's motion for summary judgment on this claim will be denied.

C. Limitation of Liability

On the reverse side of the Defendant's prescription form used by Plaintiff for ordering prostheses was a statement that read:

> Subject to the return of a device that is placed and then fails, the lab will repair or replace the device without charge for the cost of materials and workmanship or refund the original **[*9]** price paid, at the lab's option, as follows: (1) all final prosthetics up to 7 years; . . . You agree to pay all other costs of adjustment, repair and replacement of devices . . .

Defendant argues that this clause limits liability for consequential damages. Plaintiff asserts that the limitation of liability clause is not enforceable because there was no consent or acceptance of the quoted terms and the clause is unconscionable.

Consequential damages are recoverable under breach of contract claims, but parties can agree to limit remedies. 13 Pa.C.S. § 2714(c); 13 Pa.C.S. § 2719(c). "Pennsylvania law does not condition enforcement of a limitation of liability provision upon any specific form of consent, and an unsigned contract can include an enforceable agreement to limit liability if both parties manifest their approval of the terms." Valhal Corp. v. Sullivan Assocs., Inc. 44 F.3d 195, 201 (3d Cir. 1995). In commercial interactions, clauses limiting damages are generally enforced. Borden, Inc. v. Advent Ink Co.,1997 Pa. Super. LEXIS 3237, 701 A.2d 255, 262 (Pa. Super. Ct. 1997).

"A contractual provision is unconscionable if: 1) one of the parties had no meaningful choice with respect **[*10]** to the provision, and 2) the provision unreasonably favors the other party." Borden, Inc. v. Advent Ink Co.,1997 Pa. Super. LEXIS 3237, 701 A.2d 255, 264 (Pa. Super. Ct. 1997). In determining whether a commercial contract is unconscionable, the court should consider "in light of the general commercial background and the commercial needs of a particular trade, the clause is so one-sided that it is unconscionable under the circumstances." Id. at 264 (citations omitted). The

party alleging unconscionability carries the burden of proof. *Id.* Limitation of damages clauses will rarely be found unconscionable in commercial settings. *Id.* The disparity between parties in negotiating the contract is a factor in determining whether a limitation of liability clause is unconscionable. *Moscatiello v. Pittsburgh Contractors Equipment Co., 407 Pa. Super. 363, 595 A.2d 1190, 1195-96 (Pa. Super. 1991)*.

Here, whether the parties manifested consent to the clause is in question. The clause appeared on the back of Defendant's prescription form that Plaintiff used to acquire the products. There was no indication on the front of the form that the reverse side contained additional terms. Neither party presented **[*11]** evidence regarding the commercial background or the disparity between parties in negotiating the contract. Viewing the case in the light most favorable to the non-moving party, as we must in a motion for summary judgment, Defendant has not met its burden to prove that the limitation of liability clause is enforceable.

IV. Conclusion

Based on the preceding, we will grant Defendant's motion for summary judgment on counts I and III of Plaintiff's complaint and deny Defendant's motion for summary judgment on counts II and IV. We will issue an appropriate order.

/s/ William W. Caldwell

William W. Caldwell

United States District Judge

ORDER

AND NOW, this 8th day of November, 2011, upon consideration of defendant's motion for summary judgment (doc. 54) and Plaintiff's response, and pursuant to the accompanying Memorandum, it is ordered that:

1. Defendant's motion for summary judgment on Counts I and III of Plaintiff's complaint is granted.
2. Defendant's motion for summary judgment on Counts II and IV of Plaintiff's complaint is denied.

/s/ William W. Caldwell

William W. Caldwell

United States District Judge

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Goleman v. York Int'l Corp.

United States District Court for the Eastern District of Pennsylvania

August 3, 2011, Decided; August 3, 2011, Filed

CIVIL ACTION NO. 11-1328

Reporter
2011 U.S. Dist. LEXIS 85477 *

JOEL GOLEMAN v. YORK INTERNATIONAL CORP.

Core Terms

Furnace, good faith, fair dealing, alleges, statute of limitations, unjust enrichment, limited warranty, warranty, parties', injunctive relief, breach of duty, tolled, cause of action, motion to dismiss, factual allegations, duty of good faith, deceptive acts, discovery rule, contends, Igniter, fails, fraudulent concealment, consumer protection, circumstances, plaintiffs', factory, justifiable reliance, matter of law, misleading, deceptive

Counsel: **[*1]** For JOEL GOLEMAN, AN INDIVIDUAL, ON BEHALF OF HIMSELF AND ALL OTHERS SIMILARLY SITUATED, Plaintiff: BRIAN M. FELGOISE, LAW OFFICES OF BRIAN M. FELGOISE PC, JENKINTOWN, PA.

For YORK INTERNATIONAL CORPORATION, Defendant: CHRISTOPHER SCOTT D'ANGELO, LEAD ATTORNEY, MONTGOMERY, MC CRACKEN, WALKER & RHOADS, PHILADELPHIA, PA.

Judges: Michael M. Baylson, United States District Judge.

Opinion by: Michael M. Baylson

Opinion

MEMORANDUM RE: MOTION TO DISMISS

Baylson, J.

I. Introduction

Plaintiff Joel Goleman ("Goleman" or "Plaintiff") filed this putative class action against Defendant York International Corporation ("York" or "Defendant") on behalf of himself and all others similarly situated who purchased Coleman DGU Series Furnaces (the "Furnaces") containing an original "Hot Surface Igniter" ("HSI") component. Plaintiff alleges that Defendant defectively designed the original HSI and failed to notify the proposed class when Defendant designed an upgraded HSI. Specifically, Plaintiff's Complaint alleges violations of many state consumer protection laws (Count I), the Magnuson-Moss Act, *15 U.S.C. § 2301, et seq.* (Count II), and state common law, including breach of express warranty (Count III), breach of implied warranty (Count **[*2]** IV), unjust enrichment (Count V), equitable relief (Count VI), and breach of duty of good faith and fair dealing (Count VII). Plaintiff has conceded that Counts II, III, and IV are barred by the statute of limitations.

Presently before the Court is Defendant's Motion to Dismiss Plaintiff's Complaint (ECF No. 5) pursuant to *Federal Rule of Civil Procedure 12(b)(6)*. For the following reasons, Defendant's Motion to Dismiss is granted with prejudice as to Counts II-V and VII, and without prejudice as to Counts I and VI.

II. Factual and Procedural Background

According to the Complaint, in October 2000, Plaintiff, a citizen and resident of Pennsylvania, purchased and installed a Coleman Gas-Fired, High Efficiency Upflow Condensing DGU Series Furnace (the "Furnace"), model number DGU10014UA, serial number EBEM045566. Compl. ¶¶ 7, 21. Defendant is allegedly the designer, manufacturer, marketer, distributor and seller of the Furnaces. Compl. ¶¶ 8, 20. The Furnace contained an ignition source called the Hot Surface Igniter ("HSI"). Compl. ¶¶ 10, 12. The HSI as originally designed did not have a protective covering to prevent condensation build-up, which can cause the HSI to crack and prevent it **[*3]** from igniting the fuel in the Furnace to deliver heated air. Compl. ¶¶ 12-13. Plaintiff alleges that the Furnace came with a 20-year limited

warranty from the original installation date. Compl. ¶ 21.

Defendant filed with its Motion to Dismiss the affidavit of David L. Negrey (ECF No. 5, Ex. 1), to which it attached the Limited Warranty and Gas Furnace Heat Exchange Warranty (the "Limited Warranty") for the Furnace based on the serial number alleged in the Complaint. (Ex. A to Negrey Aff.) The Limited Warranty states that "Unitary Products Group (UPG) warrants this product to be free from defects in factory workmanship and material under normal use and service and will, at its option, repair or replace any parts that prove to have such defects within a period of one (1) year from the date of product installation." Id. (emphasis added). [1]

In 2003, Defendant designed an upgraded HSI with a protective casing to prevent condensation **[*4]** and dirt or dust buildup, which is compatible with the Furnaces. Compl. ¶ 14. Plaintiff alleges that Defendant did not advise owners of the Furnaces and HVAC technicians who service the Furnaces of the availability of the upgraded HSI, and failed to disclose problems with the original HSI. Compl. ¶¶ 15-17. Plaintiff further alleges that he lacked knowledge of the defect. Compl. ¶ 18.

Sometime before January 2005, Plaintiff's Furnace stopped working. Compl. ¶ 22. On an unspecified date, an HVAC technician repaired the Furnace and informed Plaintiff that the HSI had failed. Compl. ¶ 22. Five years later, on February 24, 2010, an HVAC technician who was called to repair the Furnace replaced the HSI with another HSI of the "original design." [2] Compl. ¶ 23. One week later, this HSI failed, and on March 2, 2010, the HVAC technician "again installed the original design Hot Surface Igniter." Compl. ¶ 24. Approximately three days later, the furnace was not working again, and the HVAC technician installed an upgraded HSI. Compl. ¶ 25. Plaintiff paid the HVAC technician $120 for the upgraded HSI and $275 for the labor associated with the three visits. Compl. ¶ 25. Plaintiff has had no further **[*5]** problems with the Furnace. Compl. ¶ 26.

On February 25, 2011, Plaintiff filed the Complaint against Defendant. (ECF No. 1) Defendant filed its Motion to Dismiss on April 19, 2011. (ECF No. 5) Plaintiff responded on May 9, 2011. (ECF No. 6) Defendant replied on May 16, 2011. (ECF No. 7)

III. The Parties' Contentions

Defendant raises five arguments in its motion to dismiss. First, Defendant contends that the Magnuson-Moss Act (Count II), breach of express warranty (Count III), and breach of implied warranty (Count IV) claims are barred both by a four-year statute of limitations, and because the alleged design defect arose after the expiration of the Limited Warranty. Def.'s Mem. Supp. Mot. Dismiss 4-7. Plaintiff concedes that his warranty claims are barred. Pl.'s Mem. Law Opp'n 4.

Second, Defendant contends Plaintiff's claim for unjust enrichment (Count V) fails, because it is barred by a four-year statute of limitations, which began to run when Plaintiff purchased the Furnace in October 2000. Def.'s Mem. Supp. Mot. Dismiss 7-8. Plaintiff responds that the statute of limitations was tolled by the discovery **[*6]** rule and fraudulent concealment doctrine. Pl.'s Mem. Law Opp'n 4-5. Defendant also contends that the unjust enrichment claim fails as a matter of law because the Limited Warranty is an express contract governing the parties' relationship. Id. at 8-9

Third, Defendant contends Plaintiff's claim for breach of the duty of good faith and fair dealing (Count VII) fails, because Plaintiff cannot specify a contract provision under which Defendant breached any alleged duty, and because "there is no such thing as a claim for breach of a free-standing duty of good faith and fair dealing under these circumstances." Def.'s Mem. Supp. Mot. Dismiss 9. Plaintiff responds that "every contract imposes an obligation of good faith in its performance or enforcement," and that "[h]onesty in the previous transactions (the prior repairs) would have mandated that Plaintiff be advised of the redesign of the [HSI] . . . ." Pl.'s Mem. Law Opp'n 6-7.

Fourth, Defendant contends that Plaintiff's claim under Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL") (Count I) fails, because Plaintiff did not plead facts to support his allegations as required by *Federal Rule of Civil Procedure 9(b)*. **[*7]** Def.'s Mem. Supp. Mot. Dismiss 9-11. Plaintiff responds that the *Rule 9(b)* heightened pleading standard does not apply to allegations of deceptive conduct under the UTPCPL. Pl.'s Mem. Law Opp'n 7-8. Alternatively, Defendant asserts that Plaintiff has not pled the elements of a UTPCPL claim. Def.'s Reply Mem. Supp. Mot. Dismiss 7-8.

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[1] The relationship of UPG to York is unclear. Although the Limited Warranty states that UPG provides the warranty, the copyright on the Limited Warranty is "York International Corporation 1995." Plaintiff alleged that York is a subsidiary of Johnson Controls. Compl. ¶ 8.

[2] Plaintiff alleges no facts from the period between January 2005 and February 2010.

Finally, Defendant contends that Plaintiff's claim for equitable relief (Count VI) fails, because all of Plaintiff's substantive claims should be dismissed, and there are adequate remedies at law. Plaintiff responds that equitable relief is warranted given that "Plaintiff has no adequate redress at law" and that "[t]he equitable relief being sought by Plaintiff" is information regarding the redesigned HSI, which has no exact damage calculation." Pl.'s Mem. Law Opp'n 8-9.

IV. Legal Standard

A. Jurisdiction

The Court has subject matter jurisdiction over this matter pursuant to *28 U.S.C. § 1332* (Counts I, III-VII) and *28 U.S.C. § 1331* (Count II). Pursuant to *28 U.S.C. § 1332(d)*, Plaintiff alleges that the aggregate claims of the class exceed $5,000,000, exclusive of interest and costs, and that all members of the putative class are citizens of different states **[*8]** than Defendant. *28 U.S.C. § 1332(d)(2)*.

Plaintiff Goleman is a citizen of Pennsylvania. Pursuant to *28 U.S.C. § 1332(c)(1)*, a corporation is a citizen of its state of incorporation and of the state where it has its principal place of business. Defendant York is a citizen of Wisconsin, as it is alleged to be a subsidiary of Johnson Controls, a Wisconsin company with its principal place of business in Milwaukee, Wisconsin.

B. Standard of Review for a *Rule 12(b)(6)* Motion to Dismiss

In deciding a motion to dismiss pursuant to *Federal Rule of Civil Procedure 12(b)(6)*, the court must accept as true all well-pleaded factual allegations and must construe them in the light most favorable to the non-moving party. *Phillips v. County of Allegheny, 515 F.3d 224, 228 (3d Cir. 2008)*. The Third Circuit has addressed the effect of the Supreme Court's most recent pleading-standard decisions, *Twombly v. Bell Atlantic Corp., 550 U.S. 544, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007)*, and *Ashcroft v. Iqbal, 556 U.S. 662, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009)*. See *Phillips, 515 F.3d at 233-34*. Twombly established a three-pronged approach for all civil actions: first, the court must identify the elements the plaintiff must plead to state a claim; second, the court asks whether **[*9]** the complaint sets forth factual allegations or conclusory statements; third, if the complaint sets forth factual allegations, the court must assume their veracity and draw reasonable inferences in favor of the non-moving party, but then must determine whether the factual allegations plausibly give rise to an entitlement to relief. *Santiago v. Warminster Twp., 629 F.3d 121, 130 & n.7 (3d Cir. 2010)*; see *Iqbal, 129 S. Ct. at 1950, 1953*. For the second step, the court should separate the factual and legal elements of the claims, accepting the well-pleaded facts as true and disregarding any legal conclusions. *Fowler v. UPMC Shadyside, 578 F.3d 203, 210-11 (3d Cir. 2009)*.

To state a claim, a plaintiff must allege circumstances with enough factual matter to suggest the required claim exists. *Phillips, 515 F.3d at 234*. This does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary elements of the claims. *Iqbal, 129 S. Ct. at 1949*; *Phillips, 515 F.3d at 234*. Pleading standards are not the same as standards of proof. See *Fowler, 578 F.3d at 213-14*. Whether **[*10]** a claim is plausible depends on the context, i.e. the nature of the claim asserted. *Phillips, 515 F.3d at 233*. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to reasonably infer that the defendant is liable for the misconduct alleged. *Gelman v. State Farm Mut. Auto. Ins. Co., 583 F.3d 187, 190 (3d Cir. 2009)*.

V. Discussion

A. Counts II, III, IV: Federal and State Warranty Claims

Both Defendant and Plaintiff agree that Plaintiff's warranty claims under state law and the Magnuson-Moss Act are barred by the statute of limitations. Def.'s Mem. Supp. Mot. Dismiss 4-6; Pl.'s Mem. Law Opp'n 4 ("Plaintiff concedes that his warranty claims are barred by the statute of limitations and dismisses same."). Therefore, Counts II, III, and IV will be dismissed with prejudice.

B. Count V: Unjust Enrichment

1. Statute of Limitations

Plaintiff's unjust enrichment claim (Count V) is also time-barred by the statute of limitations. Pennsylvania law imposes a four-year statute of limitations on claims of unjust enrichment. *42 Pa. Cons. Stat. Ann. § 5525(a)(4)*. "Whether a complaint is timely filed within the limitations period is a matter of law for the court to **[*11]** determine." *Sevast v. Kakouras, 591 Pa. 44, 915*

A.2d 1147, 1153 (Pa. 2007) (quoting Crouse v. Cyclops Indus., 560 Pa. 394, 745 A.2d 606, 611 (Pa. 2000)). An unjust enrichment claim "accrues when the defendant 'receives and retains benefits.'" Harry Miller Corp. v. Mancuso Chems., Ltd., 469 F. Supp. 2d 303, 319 (E.D. Pa. 2007) (Brody, J.) (quoting Konidaris v. Portnoff Law Assocs., Ltd., 884 A.2d 348, 355 (Pa. Cmwlth. Ct. 2005), rev'd in part, 598 Pa. 55, 953 A.2d 1231 (Pa. 2008)).

Here, Plaintiff alleges that he purchased the Furnace from Defendant in October 2000. Compl. ¶ 10. Thus, the statutory period began to run in October 2000, when Defendant received and retained the benefit of the sale, and ended in October 2004. However, Plaintiff asserts in his response brief that the "unjust enrichment occurred at the time that York redesigned the Hot Surface Igniter some time in 2003 and failed to advise Class Members that the original design was defective." Pl.'s Mem. Law Opp'n 5. Even if Plaintiff were correct that his claim accrued in 2003, the four-year statute of limitations still forecloses Plaintiff's claim, which he filed in February 2011.

Plaintiff contends that the statute of limitations was tolled until he discovered **[*12]** the defect, and cites Harry Miller for support. In Harry Miller, the plaintiff chemical company brought claims against a competitor company, including for unjust enrichment by use of the plaintiff's trade secrets. Harry Miller, 469 F. Supp. 2d at 319. The plaintiff invoked the same two tolling doctrines that Plaintiff invokes here—the "discovery rule" and the doctrine of fraudulent concealment—to argue that the statute of limitations did not begin running until the plaintiff learned of the competitor's conduct. Id. at 312. Each will be considered separately.

The discovery rule "triggers the tolling of the statute of limitations when the plaintiff is 'unable, despite the exercise of reasonable diligence, to discover the injury or its cause.'" Id. (quoting Mest v. Cabot Corp., 449 F.3d 502, 510 (3d Cir. 2006)). The discovery rule under Pennsylvania law applies "'in only the most limited of circumstances.'" Id. at 313 (quoting Dalrymple v. Brown, 549 Pa. 217, 701 A.2d 164, 171 (Pa. 1997)). To successfully toll the statute, the plaintiff "bears the burden of demonstrating reasonable diligence in determining the existence of injury and cause of injury." Id. (citing Swietlowich v. County of Bucks, 610 F.2d 1157, 1162 (3d Cir. 1979)).

The **[*13]** fraudulent concealment doctrine applies where the defendant "committed an 'affirmative and independent act of concealment that would divert or mislead the plaintiff,'" which "'causes the plaintiff to relax his vigilance or deviate from the right of inquiry.'" Id. at 316 (quoting Mest, 449 F.3d at 516, 517).

In Harry Miller, the court rejected the plaintiff's argument that the discovery rule applied, because the plaintiff had not shown reasonable diligence in ascertaining the cause of its injury. Id. at 314. Rather, the plaintiff "remained content with its own ignorance," and "developed no serious strategy" to investigate the problem. Id. at 314-15. Likewise, the fraudulent concealment doctrine did not apply because the plaintiff lacked evidence that the defendant "communicated directly with Miller or took any affirmative steps that would mislead Miller," and "no evidence that anyone at [the defendant company] ever spoke to anyone at Miller. . . or had any opportunity to make misleading remarks." Id. at 316.

Judge Brody contrasted the facts of Harry Miller with the facts of Mest v. Cabot Corp., in which the plaintiffs successfully argued the statute of limitations was tolled. In Mest, **[*14]** farmers who alleged that factory emissions made their cows ill demonstrated reasonable diligence in discovering the cause of the injury by "swiftly hir[ing] agricultural experts, contact[ing] environmental regulatory agencies, and retain[ing] university scientists" when they suspected their cows were sick. Id. at 314 (citing Mest, 449 F.3d at 508-09). Moreover, the defendant factory acted affirmatively by "assur[ing] a subset of the plaintiff farmers that the factory was not causing the cows' symptoms." Id. at 316 (citing Mest, 449 F.3d at 516). Therefore, the doctrine of fraudulent concealment tolled the statute of limitations as to the farmers to whom the factory communicated this misinformation, but not as to farmers who had not communicated directly with the factory owner. Id. at 316 (citing Mest, 449 F.3d at 516-17).

Here, Plaintiff has not alleged any facts to support application of the discovery rule or the doctrine of fraudulent concealment. Indeed, Plaintiff's Complaint pleads no facts between 2005 and 2010. Plaintiff does not allege that he took steps to discover even the "existence of injury," let alone the "cause of injury," as required under Pennsylvania law. See Harry Miller, 469 F. Supp. 2d at 313 **[*15]** (emphasis added). Rather, Plaintiff remained ignorant of the existence of any problem with his Furnace for years and developed no strategy to determine the cause of the problem. Plaintiff also did not plead facts showing that Defendant communicated an affirmative misrepresentation or made

misleading remarks directly to Plaintiff about the HSI. The boilerplate allegations that Defendant engaged in "fraudulent acts of concealment" and "refus[ed] to disclose facts known to Defendant about the defect in the Hot Surface Igniter" are insufficient. Compl. ¶ 19. In the absence of supporting factual allegations, no tolling doctrine applies to Plaintiff's unjust enrichment claim.

2. Unjust Enrichment Barred as a Matter of Law

Alternatively, even if the unjust enrichment claim were not time-barred, Plaintiff has not stated a claim as a matter of law because the relationship between the parties is governed by contract. "Under Pennsylvania law, 'the quasi-contractual doctrine of unjust enrichment [is] inapplicable when the relationship between the parties is founded on a written agreement or express contract.'" *Hershey Foods Corp. v. Ralph Chapek, Inc., 828 F.2d 989, 999 (3d Cir. 1987)* (quoting *Benefit Trust Life Ins. Co. v. Union Nat. Bank, 776 F.2d 1174 (3d Cir. 1985))*. **[*16]** Where the claims "fall within the scope of those individual and separate agreements into which [the parties] entered," "recovery is limited to the measure provided in the contract." Id. For example, in *Ruthrauff, Inc. v. Ravin, Inc., 2006 PA Super 352, 914 A.2d 880, 893 (Pa. Super. Ct. 2006)*, a heating subcontractor whose contract with the general contractor included a limited warranty sued for unjust enrichment. *Id. at 893*. The court held that the unjust enrichment claims stood only as to work "performed outside any promises made in the written contractual documents." Id.

Here, Defendant has attached the Limited Warranty to its Motion to Dismiss. The Court may consider the Limited Warranty as a document integral to the Complaint. The Limited Warranty governs the relationship between Plaintiff and Defendant concerning the purchase and sale of the Furnace. Because Plaintiff cannot state an unjust enrichment claim as a matter of law, Count V is dismissed with prejudice.

C. Count VII: Breach of Duty of Good Faith and Fair Dealing

Plaintiff's claim that Defendant breached its duty of good faith and fair dealing also must be dismissed because it does not state a valid cause of action. Pennsylvania courts have **[*17]** found an implied covenant of good faith and fair dealing stems from the *Restatement (Second) of Contracts § 205*, which provides: "Every contract imposes upon each party a duty of good faith and fair dealing in its performance and its enforcement." [3] The Uniform Commercial Code ("U.C.C.") similarly contains an implied duty of good faith and fair dealing pursuant to *13 Pa. Cons. Stat. Ann. § 1203*. *Somers v. Somers, 418 Pa. Super. 131, 613 A.2d 1211, 1213 (Pa. Super. 1992)* (the U.C.C. requires "[h]onesty in fact in the conduct or transaction concerned"). However, the courts generally apply "'the U.C.C.'s good faith requirements in aid and furtherance of the parties' agreement, not to override the parties' agreement for reasons of fairness, policy, or morality.'" *Duquesne Light Co. v. Westinghouse Elec. Corp., 66 F.3d 604, 617 (3d Cir. 1995)* (quoting Steven J. Burton, Symposium: The Revision of Article 2 of the Uniform Commercial Code : Good Faith in Articles 1 and 2 of the U.C.C.: The Practice View, *35 Wm. & Mary L. Rev. 1533, 1534 (1994)*). "[C]ourts generally utilize the good faith duty as an interpretive tool to determine the parties' justifiable expectations, and do not enforce an independent duty divorced **[*18]** from the specific clauses of the contract." *Id. at 617* (citation and internal quotation marks omitted). But see *Creeger Brick & Bldg. Supply, Inc. v. Mid-State Bank & Trust Co., 385 Pa. Super. 30, 560 A.2d 151, 153-54 (Pa. Super. Ct. 1989)* (discussing that Pennsylvania recognizes a duty of good faith only "in limited situations," including between insurers and insured, and between franchisors and franchisees).

For example, in *Duquesne Light*, several electric utility companies brought claims against the defendant arising out of their contract for sale of nuclear steam supply systems, including a claim for breach of the duty of good faith and fair dealing. *Duquesne Light, 66 F.3d at 607*. The plaintiffs claimed they expected the nuclear steam supply systems would last 40 **[*19]** years, when in fact the contract contained an explicit and limited warranty for one to three years, depending on certain circumstances. [4] *Id. at 615*. The district court dismissed the breach of the duty of good faith claim because the

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[3] The Supreme Court of Pennsylvania has not expressly adopted *Section 205*, although the Pennsylvania Superior Court has done so. See ***Ash v. Cont'l Ins. Co., 593 Pa. 523, 932 A.2d 877, 883 n.2 (Pa. 2007)***; *Baker v. Lafayette College, 350 Pa. Super. 68, 504 A.2d 247, 255-56 (Pa. Super. Ct. 1986)*, aff'd, *516 Pa. 291, 532 A.2d 399 (Pa. 1987)* (explaining that a defendant's "obligation to act in good faith extends only to the performance of those contractual duties it has chosen to assume").

[4] The plaintiffs' cause of action for breach of warranty also failed, because "latent defects discovered after the term of the warranty are not actionable." *Duquesne Light, 66 F.3d at 616* (citations and internal quotation marks omitted).

plaintiffs could not demonstrate that a good faith duty arose from any contract provision. *Id. at 617*. The Third Circuit affirmed, holding that "[i]n the absence of a dispute about the parties' reasonable expectations under a particular term of the contract," "we do not believe that Pennsylvania courts would impose an independent duty of good faith not tied to a contractual term." *Id. at 618*. The court rejected the plaintiffs' "attempts to read into the contract a provision which it neither bargained for nor attained—a guarantee of 40 years" by alleging that the defendant seller had a duty of good faith and fair dealing to provide a longer warranty. Id.

Recently, several courts have held there is no independent cause of action **[*20]** for breach of a duty of good faith and fair dealing under Pennsylvania law. In *Cummings v. Allstate Ins. Co., No. Civ. A. 11-02691, 2011 U.S. Dist. LEXIS 74349, 2011 WL 2681517 (E.D. Pa. July 11, 2011)* (Kelly, J.), the defendant insurer contended that a breach of the duty of good faith and fair dealing was merely part of a breach of contract claim. *2011 U.S. Dist. LEXIS 74349, [WL] at *4*. Judge Kelly agreed, "hold[ing] that, under Pennsylvania law, there is no separate cause of action for breach of the duty of good faith and fair dealing and that such a claim is subsumed within a breach of contract claim." *2011 U.S. Dist. LEXIS 74349, [WL] at *5* (dismissing with prejudice claim for breach of the duty of good faith and fair dealing). See also *Zaloga v. Provident Life & Accident Ins. Co. of Am., 671 F. Supp. 2d 623, 631 (M.D. Pa. 2009)* (Kosik, J.) ((citing *Birth Center v. St. Paul Cos., Inc., 567 Pa. 386, 787 A.2d 376, 385-86 (Pa. 2001)* ("there is no independent cause of action for a breach of the covenant of good faith and fair dealing-arising in contract-in Pennsylvania because such breach is merely a breach of contract."); *LSI Title Agency, Inc. v. Evaluation Servs., Inc., 2008 PA Super 126, 951 A.2d 384, 391 (Pa. Super. Ct. 2008)* ("A breach of such covenant is a breach of contract action, not an independent **[*21]** action for breach of a duty of good faith and fair dealing.").

Until the Pennsylvania Supreme Court holds otherwise, this Court is inclined to conclude there is no independent cause of action for breach of a duty of good faith and fair dealing. However, even if such a cause of action exists under Pennsylvania law, Plaintiff's claim is barred by the terms of the parties' agreement. As in *Duquesne Light*, this case is governed by an express and limited warranty. Plaintiff cannot assert "breach of the duty of good faith and fair dealing" as a back-door attempt to extend the Limited Warranty beyond its one-year expiration date. See *Duquesne Light, 66 F.3d at 616-18*. Therefore, the Court will dismiss Count VII with prejudice.

D. Count I: Violation of Pennsylvania Consumer Protection Law

Plaintiff also alleges violations of the consumer protection laws in all the states and territories where members of the putative class resides. Because Plaintiff is a resident of Pennsylvania, the Court considers only whether he has stated a claim for violation of the Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), *73 Pa. Stat. Ann. §§ 201-1 et seq*. [5]

Plaintiff has not adequately stated a UTPCPL claim. The UTPCPL "provides a private right of action for '[a]ny person who purchases. . . goods or services primarily for personal, family or household purposes and thereby suffers any ascertainable loss of money or property' on account of the seller's unfair or deceptive acts or practices." *Gardner v. State Farm Fire & Cas. Co., 544 F.3d 553, 564 (3d Cir. 2008)* (quoting *73 Pa. Stat. Ann. § 201-9.2(a)*). "A plaintiff alleging deceptive conduct may proceed without satisfying the particularity requirement of *Federal Rule of Civil Procedure 9(b)*." *Vassalotti v. Wells Fargo Bank, N.A., 732 F. Supp. 2d 503, 511 (E.D. Pa. 2010)* (Brody, J.) (citing *Seldon v. Home Loan Servs., Inc., 647 F. Supp. 2d 451, 469-70 (E.D. Pa. 2009)* (Yohn, J.). Therefore, **[*23]** *Rule 8*, as interpreted by the Supreme Court in *Iqbal, 129 S. Ct. at 1949*, governs this claim.

Justifiable reliance is an element of any private plaintiff's cause of action under the UTPCPL. *Hunt v. U.S. Tobacco Co., 538 F.3d 217, 226 (3d Cir. 2008)*; *Yocca v. Pittsburgh Steelers Sports, Inc., 578 Pa. 479, 854 A.2d 425, 438 (Pa. 2004)*. In *Yocca*, the plaintiffs, season ticket holders, sued the Pittsburgh Steelers under the UTPCPL for allegedly making false statements in its brochure concerning the sale of season tickets. *Id. at 427-432*. The Pennsylvania Supreme Court held that the plaintiffs did not state a UTPCPL claim because they had not pled "justifiable"

[5] Plaintiff should have pled allegations on **[*22]** behalf of the putative class members separately from his own claims. Plaintiff must establish he has standing to bring his lawsuit, because "a plaintiff who lacks the personalized, redressable injury required for standing to assert claims on his own behalf would also lack standing to assert similar claims on behalf of a class." *Holmes v. Pension Plan of Bethlehem Steel Corp., 213 F.3d 124, 135 (3d Cir. 2000)*.

reliance on any representations made prior to their entry into the purchasing agreement, which explicitly "superceded all of the parties' previous representations and agreements," including the brochure. *Id. at 439*. Because the plaintiffs' allegations did not establish the element of justifiable reliance, the court affirmed the trial court's dismissal of the plaintiffs' UTPCPL claims. Id.

In his response brief, Plaintiff clarifies that he has alleged a "claim under the UTPCPL's catchall provision, which prohibits deceptive conduct generally." Pl.'s **[*24]** Mem. Law Opp'n 7. To state a claim under the catchall provision, *73 Pa. Stat. Ann. § 201-2(4)(xxi)*, a plaintiff must allege three elements: (1) "facts showing a deceptive act, that is conduct that is likely to deceive a consumer acting reasonably under similar circumstances"; (2) "justifiable reliance, in other words that he justifiably bought the product in the first place (or engaged in some other detrimental activity) because of the defendants' misrepresentation or deceptive conduct"; and (3) "that this justifiable reliance caused ascertainable loss." *Vassalotti, 732 F. Supp. 2d at 510-11* (quoting *Seldon, 647 F. Supp. 2d at 470*). A plaintiff must plead facts alleging a specific deceptive act rather than a general failure to disclose information.

For example, in Vassalotti, the plaintiff mortgagor stated a UTPCPL claim against the defendant lender by alleging that the lender made specific misrepresentations in a letter about the loan modification program and in the loan modification agreement; that plaintiff relied on these terms in deciding to execute the agreement; and that her reliance caused her to suffer losses including increased monthly payments, late fees, and attempted foreclosure **[*25]** of her property. *Id. at 511* (denying motion to dismiss the UTPCPL claim). By contrast, in *Rubenstein v. Dovenmuehle Mortg., Inc., No. 09-721, 2009 U.S. Dist. LEXIS 100656, 2009 WL 3467769 (E.D. Pa. Oct. 28, 2009)* (Dalzell, J.), plaintiff homeowners alleged that the defendant mortgage company "failed immediately to disclose that they did not have plaintiffs' complete payment history" related to their mortgage loan, but did not allege that the defendant committed any specific deceptive act, and thus failed to state a claim. *2009 U.S. Dist. LEXIS 100656, [WL] at *6* (granting motion to dismiss the UTPCPL claim).

Here, Plaintiff has not alleged justifiable reliance or a specific deceptive act by Defendant. Rather, the Complaint alleges generally that "by advertising and marketing the York products in various media, including broadcasts, website and written promotional and other materials, Defendants misled consumers about the efficacy of the Products." Compl. ¶ 37. Plaintiff also makes a legally conclusory allegation that "Defendants intentionally engaged in these deceptive acts and made false or misleading representations, capable of causing Plaintiffs and Class Members damages if Plaintiffs and/or the Class relied upon these representations." Compl. **[*26]** ¶ 37. However, Plaintiff has not pled any facts alleging that Defendant committed a specific deceptive act related to the Furnace and/or the HSI component. See *Rubenstein, 2009 U.S. Dist. LEXIS 100656, 2009 WL 3467769, at *6*. Plaintiff also has not alleged that he justifiably relied upon any specific deceptive statements that caused him to suffer harm. See *Yocca, 854 A.2d at 439*. Therefore, Plaintiff's existing factual allegations do not state a plausible UTPCPL claim.

Additionally, although the Defendant did not raise the statute of limitations as to the consumer protection claim, the Court concludes sua sponte that Plaintiff's UTPCPL claim is probably time-barred. "The statute of limitations for UTPCPL claims is six years." *Drelles v. Mfrs. Life Ins. Co., 2005 PA Super 249, 881 A.2d 822, 831 (Pa. Super. Ct. 2005)* (citing *42 Pa. Cons. Stat. Ann. § 5525(8)*). The "statute of limitations begins to run as soon as the right to institute and maintain a suit arises, which generally is when the injury was inflicted." Id. (citing *Fine v. Checcio, 582 Pa. 253, 870 A.2d 850, 857 (Pa. 2005)*. "'Mistake, misunderstanding, or lack of knowledge in themselves do not toll the running of the statute,'" although the discovery rule and the doctrine of fraudulent **[*27]** concealment may do so. Id. (quoting *Fine, 870 A.2d at 857*). However, as discussed in Section V.B.1, Plaintiff has not pled facts to show that either tolling exception applies to this case. Plaintiff's Complaint is deficient, and includes no facts between January 2005 and February 2010.

Accordingly, Count I will be dismissed without prejudice. Although the Court doubts Plaintiff can plead a UTPCPL claim, the Court will grant Plaintiff the opportunity to amend his Complaint.

E. Count VI: Injunctive Relief

Lastly, Plaintiff's request for injunctive relief also fails to survive the motion to dismiss. "An injunction is 'an extraordinary remedy, which should be granted only in limited circumstances.'" *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co., 290 F.3d 578, 586 (3d Cir. 2002)* (quoting *Instant Air Freight Co. v. C.F. Air Freight, Inc., 882 F.2d 797, 800*

(3d Cir. 1989)). "Injunctive relief will lie where there is no adequate remedy at law." *Maritrans GP Inc. v. Pepper, Hamilton & Scheetz, 529 Pa. 241, 602 A.2d 1277, 1286 (Pa. 1992)* (citation omitted).

Under Pennsylvania law, a party seeking injunctive relief "'must establish that his right to relief is clear, that an injunction **[*28]** is necessary to avoid an injury that cannot be compensated by damages, and that greater injury will result from refusing rather than granting the relief requested.'" *Kuznik v. Westmoreland County Bd. of Comm'rs, 588 Pa. 95, 902 A.2d 476, 489 (Pa. 2006))* (quoting *Harding v. Stickman, 823 A.2d 1110, 1111 (Pa. Cmwlth. Ct. 2003)*. In *Boring v. Google, Inc., 598 F. Supp. 2d 695 (W.D. Pa. 2009)* (Hay, M.J.), aff'd in part, rev'd in part on other grounds, *362 F. App'x 273 (3d Cir. 2010)* (non-precedential), plaintiffs asserted numerous claims under Pennsylvania law against Internet search engine Google, which allegedly had accessed and published photographs of their private property. *Id. at 698-99*. The district court dismissed all of the plaintiffs' other claims before dismissing the claim for injunctive relief, and then found that the plaintiff had not established a clear right to relief. *Id. at 704* ("Where not one of the other claims is sufficient to survive the Defendant's Motion to Dismiss, the assertion of a right to injunctive relief also fails."). The Third Circuit affirmed the dismissal of nearly all of the claims, including the claim for injunctive relief. *Boring, 362 F. App.'x at 282* (reversing **[*29]** and remanding the trespass claim to the district court).

Here, as in *Boring*, Plaintiff has not alleged a valid cause of action for injunctive relief, because he has not established a clear right to relief. Id. None of Plaintiff's other claims have survived dismissal. Furthermore, Plaintiff has not alleged why a damages remedy would not be adequate to compensate Plaintiff if Defendant bears any liability. Because Plaintiff's existing factual allegations do not plausibly state a claim for injunctive relief, Defendant's motion to dismiss Count VI under *Rule 12(b)(6)* is granted without prejudice. [6]

[6] Plaintiff should bear in mind if filing an Amended Complaint that the UTPCPL authorizes only the Attorney General and District Attorney, not a private plaintiff, to seek temporary or permanent injunctive relief against a defendant. *73 Pa. Stat. Ann. §201-4*. See also *Weinberg v. Sun Co., Inc., 565 Pa. 612, 777 A.2d 442, 446* ("There is no authority which would permit a private plaintiff to pursue an advertiser because an advertisement might deceive members of the audience and might influence a purchasing decision when the plaintiff himself was neither deceived nor influenced.").

VI. Conclusion

For the above reasons, **[*30]** Defendant's motion to dismiss will be granted with prejudice as to Counts II-V and VII, and without prejudice as to Counts I and VI. If Plaintiff can allege sufficient facts to overcome the deficiencies identified in this Memorandum, he may file an Amended Complaint. If he files an Amended Complaint, Plaintiff should separate the class allegations pursuant to *Fed. R. Civ. P. 23* from the allegations in support of his own claims.

An appropriate Order follows.

ORDER RE: MOTION TO DISMISS

AND NOW, on this 3rd day of August, 2011, upon careful consideration of Defendant's Motion to Dismiss Plaintiff's Complaint, and Plaintiff's response thereto, and for the reasons in the accompanying Memorandum of Law, it is hereby ORDERED that Defendant's Motion to Dismiss (ECF No. 5) is GRANTED. Plaintiff Goleman is granted leave to file an amended complaint within fourteen (14) days of this Order to cure the deficiencies identified in the Memorandum.

BY THE COURT:

/s/ Michael M. Baylson

Michael M. Baylson, U.S.D.J

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In re Shop-Vac Mktg. & Sales Practices Litig.

United States District Court for the Middle District of Pennsylvania

July 17, 2014, Decided; July 17, 2014, Filed

MDL No. 2380; No. 4:12-md-2380

Reporter
2014 U.S. Dist. LEXIS 98075 *; 2014 WL 3557189

IN RE: SHOP-VAC MARKETING AND SALES PRACTICES LITIGATION. THIS DOCUMENT RELATES TO: ALL CASES.

Prior History: *In re Shop-Vac Mktg. & Sales Practices Litig., 2013 U.S. Dist. LEXIS 7023 (M.D. Pa., Jan. 17, 2013)*

Core Terms

motion to dismiss, vacuums, notice, Plaintiffs', horsepower, allegations, consumer, representations, warranty, peak, tank, packaging, implied warranty, choice of law, express warranty, promises, judicial notice, warranty claim, amended complaint, bargain, affirmation of fact, notice of breach, consumer fraud, state law, misrepresentations, products, conform, unfair, buyer, named plaintiff

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For Lowe's Companies, Inc., Defendant: Michael Lawrence Mallow, Michael Brian Shortnacy, LOEB & LOEB LLP, LOS ANGELES, CA; Thomas G. Collins, Buchanan Ingersoll & Rooney PC, Harrisburg, PA.

Judges: Yvette Kane, United States District Judge.

Opinion by: Yvette Kane

Opinion

MEMORANDUM

Before the Court is Defendants' motion to dismiss Plaintiffs' second consolidated amended complaint. (Doc. No. 102.) For the reasons that follow, the Court will grant Defendants' motion **[*4]** in part, and deny it in part.

I. BACKGROUND

Plaintiffs filed the first consolidated amended complaint in the above-captioned multidistrict litigation (MDL)[1] on February 19, 2013, alleging that Defendants Shop-Vac Corporation and Lowe's Home Improvement made fraudulent and misleading representations regarding the peak horsepower and tank capacity on Shop-Vac vacuums. (Doc. No. 62.) Defendants moved to dismiss the first consolidated amended complaint (Doc. No. 68) and, on June 20, 2013, the Court heard oral argument on the motion. The Court subsequently dismissed Plaintiffs' complaint without prejudice on August 9, 2013. (Doc. No. 94.) The dismissal was primarily premised on Plaintiffs' failure to allege with specificity the products they purchased, the time and place in which they purchased the products, and the exact nature of the alleged promises and warranties contained on the packaging.[2] (Id.) The Court also found that Plaintiffs failed to allege that they provided pre-litigation notice to Defendants regarding the breach of warranty claims. (Id.)

On September 12, 2013, Plaintiffs filed a second consolidated amended complaint ("SCAC"). (Doc. No. 97.) The SCAC brings essentially the same allegations as the earlier complaint, but now contains specific allegations regarding the products purchased, the time and place of the purchases, and the specific nature of the representations on the Shop-Vac packaging. (Id.) The SCAC contains only three named Plaintiffs: Alan McMichael, a Florida resident who purchased his Shop-Vac at a Lowe's store in Florida; Andrew Harbut, a Missouri resident who purchased his Shop-Vac at a Lowe's store in Missouri; and Kris Reid, a California resident who purchased his Shop-Vac at a Stock Building Supply in California. (Id. ¶¶ 7-9.)

As in the prior complaint, Plaintiffs allege that they relied on misrepresentations made by Shop-Vac regarding the peak horsepower and tank capacity of the company's vacuum cleaners. (Doc. No. 97 ¶¶ 7-9.) Specifically, Plaintiffs allege that Shop-Vac misleads consumers by representing **[*6]** that its vacuums are capable of reaching a peak horsepower that is impossible to attain in actual use by consumers. (Id. ¶¶ 14-45.) Plaintiffs also allege that Shop-Vac makes misleading representations about the vacuums' tank capacities, because, in actual operation, the vacuums stop working when their tanks reach between 47% and 83% of their stated capacity. (Id. ¶¶ 46-49.) Plaintiffs assert that these representations are misleading to reasonable consumers. (Id. ¶¶ 17, 49.) Plaintiffs also allege that Defendant Lowe's sells a line of Shop-Vac vacuums with the company's blue trade dress that contain identical misrepresentations on the boxes, as well as in advertisements and buyer's guides for its "Lowe's Shop-Vacs." (Id. ¶¶ 50-55.)

Plaintiffs assert four separate counts in the SCAC: (1) violations of various state consumer fraud laws; (2)

[1] The case was transferred to this court by order of the Panel on Multidistrict Litigation on August 16, 2012. (Doc. No. 1.)

[2] In particular, **[*5]** the Court found the first amended complaint insufficient pursuant to *Rule 9(b) of the Federal Rules of Civil Procedure*, which places a heightened pleading standard on claims based in fraud or mistake.

violations of the Magnuson-Moss Warranty Act; (3) breach of express warranty, and (4) breach of the implied warranty of merchantability. (Doc. No. 97.) Plaintiffs seek to represent a class of consumers in all states — other than New Jersey — who purchased any Shop-Vac vacuum within the relevant statute of limitations period. (Id. ¶ 56.) They also seek **[*7]** to represent a subclass of all consumers who purchased their Shop-Vac at Lowe's home improvement stores. (Id. ¶ 57.) On October 25, 2013, Defendants filed a motion to dismiss pursuant to *Federal Rules of Civil Procedure 12(b)(1)* and *12(b)(6)*. (Doc. No. 102.) Once the motion was fully briefed, the Court held oral argument on the motion on Monday, May 19, 2014. (Doc. No. 114.) The motion is ripe for disposition.

II. LEGAL STANDARD

A motion to dismiss filed pursuant to *Federal Rule of Civil Procedure 12(b)(6)* tests the legal sufficiency of the complaint. *Kost v. Kozakiewicz, 1 F.3d 176, 183 (3d Cir. 1993)*. In reviewing a motion to dismiss, a court may "consider only the allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim." *Lum v. Bank of America, 361 F.3d 217, 221 n.3 (3d Cir. 2004)*. Consistent with the Supreme Court's ruling in *Bell Atlantic Corporation v. Twombly,* and *Ashcroft v. Iqbal*, the Third Circuit requires district courts to engage in a two-part analysis when reviewing a *Rule 12(b)(6)* motion: (1) First, a court should separate the factual and legal elements of a claim, accepting well-leaded factual **[*8]** matter and disregarding any legal conclusions; (2) Second, a court should determine whether the remaining well-pleaded facts sufficiently demonstrate that a plaintiff has a "plausible claim" for relief. *Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009)*.

Although the *Rule 12(b)(6)* standard does not require "detailed factual allegations," there must be a "'showing,' rather than a blanket assertion of entitlement to relief. . . . '[F]actual allegations must be enough to raise a right to relief above the speculative level.'" *Phillips v. Cnty. of Allegheny, 515 F.3d 224, 231-32 (3d Cir. 2008)* (quoting *Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007))*. Put otherwise, a civil complaint must "set out 'sufficient factual matter' to show that the claim is facially plausible." *Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009)* (quoting *Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009))*.

III. DISCUSSION

This memorandum will first address three preliminary issues raised by Defendants' motion: (1) Defendants' request for judicial notice, (2) choice of law, and (3) standing. The memorandum will then address Plaintiffs' four causes of action in the following order: (1) breach of express **[*9]** warranty; (2) breach of implied warranty; (3) violations of the Magnuson-Moss Warranty Act; and (4) consumer fraud claims.

A. Judicial notice

In conjunction with their motion to dismiss, Defendants ask the Court to take judicial notice of certain documents in ruling upon the motion. (Doc. Nos. 104-106.) Specifically, they ask the Court to take notice of (1) Shop-Vac packaging [3] purportedly utilized on the vacuums the Plaintiffs allegedly purchased, images of which are not included in Plaintiffs' complaint, and (2) a complaint in a separate lawsuit that raises substantially similar claims. (Id.) Plaintiffs object to judicial notice of the documents, particularly the packaging. (Doc. No. 107 at 9-11.) Plaintiffs contest that they "cannot at this time verify [the packaging's] accuracy and therefore must object to its authenticity." (Id. at 9.)

"Generally speaking, a trial court has discretion to address evidence outside the complaint when ruling on a motion to dismiss." *Pryor v. NCAA, 288 F.3d 548, 559-60 (3d Cir. 2002)*. A court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document. *Pension Ben. Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993)*. "Otherwise, a plaintiff with a legally deficient claim could survive a motion to dismiss simply by failing to attach a dispositive document on which it relied." Id. "While the [Federal Rules of Evidence] allow a court to take judicial notice at any stage of the proceeding, *Fed.R.Evid. 201(f)*, . . . it should be done sparingly at the pleadings stage. Only in the clearest of cases should a district court reach outside the pleadings for facts necessary to resolve a case at that point." *Victaulic*

[3] Defendants argue that if the Court took judicial notice of the packaging, it would mandate dismissal of Plaintiffs' allegations that the Shop-Vac promised a tank capacity of sixteen gallons. (Doc. No. 103 at 26-28.) Specifically, according to the images of the boxes provided by Defendants, the packaging states that, regarding the tank, "working capacity **[*10]** may vary by use." (Doc. No. 106-1.) Therefore, Defendants ask to the Court to conclude that the packaging expressly disclaimed and therefore did not promise a 16-gallon capacity. (Doc. No. 103 at 26-28.)

Co. v. Tieman, 499 F.3d 227, 236 (3d Cir. 2007) **[*11]** (citing Fed.R.Evid. 201(b)). "For all practical purposes, judicially noticing a fact is tantamount to directing a verdict against a party as to the noticed fact." LaSalle Nat. Bank v. First Conn. Holding Grp., LLC, 287 F.3d 279, 290 (3d Cir. 2002) (citing Werner v. Werner, 267 F.3d 288, 295 (3d Cir. 2001)).

Applying the standard for judicial notice to the vacuum packaging provided by Defendants, there is no doubt that Plaintiffs' claims are "based on the document [sought to be noticed]," as the allegations in the complaint directly concern the assertions on the vacuum packaging. However, Plaintiffs do raise an authenticity objection, albeit a non-specific one, and authenticity objections are generally dispositive regarding requests for judicial notice. See, e.g., Brown v. Hain Celestial Grp., Inc., 913 F. Supp. 2d 881, 893-94 (N.D. Cal. 2012). Accordingly, in consideration of the Third Circuit's reluctance to convert motions to dismiss into motions for summary judgment, and Plaintiffs' objections to judicial notice, the Court will decline to exercise its discretion to take notice of the packaging and its contents at this time. See Pryor, 288 F.3d at 559-60 ("[D]ocuments whose contents **[*12]** are alleged in the complaint and whose authenticity no party questions, but which are not physically attached to the pleading, may be considered.") (emphasis added). The Court finds that these additional questions regarding the packaging and its bearing on Plaintiffs' allegations are better suited for disposition after the parties conduct discovery.

Regarding Defendants' request that the Court take judicial notice of an earlier complaint filed in another action, which Plaintiffs' counsel insist they had no part in drafting (Doc. No. 107 at 21), the Court finds this document has no bearing on the Court's disposition of the motion to dismiss and will therefore decline to take notice.

B. Choice of law

In the Court's order on Defendants' first motion to dismiss, it declined to conduct a choice of law analysis:

> Defendants urge the Court to engage in a detailed choice-of-law analysis in ruling on their motion to dismiss. The Court, however, declines to do so at this stage, because resolution of the instant motion to dismiss does not require such analysis. Instead, the Court will focus on the pleading requirements set forth in Rule 8 and 9 of the Federal Rules of Civil Procedure, which apply **[*13]** irrespective of the choice-of-law analysis.

(Doc. No. 94 at 6 n.4). In their second motion to dismiss, Defendants assert that, should the Court find a choice of law analysis necessary, the SCAC contains sufficient facts for the Court to conclude that the law of the states in which the three named Plaintiffs purchased their vacuums (Florida, Missouri, and California) should govern those respective claims. (Doc. No. 103 at 17-18.) Plaintiffs object, arguing that a choice of law analysis is premature at the motion to dismiss stage. (Doc. No. 107 at 22-24.) Plaintiffs also contend that such analysis is unnecessary because of similarities in the respective states' laws. (Id.)

In the Third Circuit, a court "must apply an individualized choice of law analysis to each of plaintiff's claims." Georgine v. Amchem Prods., Inc., 83 F.3d 610, 627 (3d Cir. 1996). A federal court sitting in diversity jurisdiction must apply the forum state's choice of law rules. Warriner v. Stanton, 475 F.3d 497, 499-500 (3d Cir. 2007). The forum state in an MDL proceeding is the district court where the action was originally filed, in this case, New Jersey.[4] See In re MTBE Prods. Liab. Litig., 175 F.Supp.2d 593, 606 n.20 (S.D.N.Y. 2001). **[*14]** Due to the factual inquiry that may be necessary to decide choice of law questions, "it can be inappropriate or impossible for a court to conduct that analysis at the motion to dismiss stage when little or no discovery has taken place." In re Samsung DLP Television Class Action Litig., No. 07-2141, 2009 U.S. Dist. LEXIS 100065, 2009 WL 3584352, at *3 (D.N.J. Oct. 27, 2009). Nonetheless, "[s]ome choice of law issues may not require a full factual record and may be amenable to resolution on a motion to dismiss." Harper v. LG Elecs. USA, Inc., 595 F.Supp.2d 486, 491 (D.N.J. 2009). A pre-requisite to a choice of law analysis is that a conflict in the laws actually exist; courts have noted that before "entangling itself in messy issues of conflict of laws a court ought to satisfy itself that there actually is a difference between the relevant laws of the different states." Jean v. Dugan, 20 F.3d 255, 260 (7th Cir. 1994)

Defendants encourage the Court to conduct this analysis in conjunction with the motion to dismiss, but do not highlight for the Court the conflicts in potentially

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[4] Defendants argue that because Plaintiff Reid voluntarily dismissed his earlier case, it was technically never transferred to this Court and thus Pennsylvania, rather than New Jersey, choice of law principles should apply to his claim (Doc. No. 103 at 18 n.2). Because the Court will decline to perform **[*15]** a choice of law analysis at this stage, it will not address this dispute.

applicable state laws, nor do they address how any differences are material to the Court's disposition of the pending motion. Thus, because it does not appear that a choice of law analysis is dispositive of any of the issues currently before the Court, the Court will defer ruling on the choice of law issue until the parties present a factual record and more substantive briefing on the issue. See *In Re Hypodermic Prods. Antitrust Litig., No. 1730, 2007 U.S. Dist. LEXIS 47438, 2007 WL 1959225, at *16 (D.N.J. June 29, 2007)* ("[T]he anticipated complexity of a choice-of-law analysis may itself be a factor in determining the certifiability of the class.").

C. Standing/actual injury

Next, Defendants argue that Plaintiffs' claims must be dismissed because Plaintiffs have not alleged an injury in fact, and thus lack standing to sue.[5] (Doc. No. 103 at 18-22.) Defendants' position is that Plaintiffs have not suffered any injury; rather, "they paid for a wet/dry vacuum and received a wet/dry **[*16]** vacuum, which they used without suffering any harm." (Doc. No. 103 at 19.) To have standing to sue, a "plaintiff must have suffered an 'injury in fact' — an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan v. Defenders of Wildlife, 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992)* (citations, internal quotation marks, and footnote omitted).

The Court disagrees with Defendants' assertion and finds Plaintiffs sufficiently allege an injury, **[*17]** in that the product they purchased was not as promised and bargained for. Specifically, Plaintiffs bargained for more than a functional vacuum; they bargained for a vacuum with certain specifications regarding power and tank size. (Doc. No. 97 ¶¶ 14-37.) Plaintiffs allege that Defendants "grossly misrepresent the horsepower the vacuums can reach under any conditions for any length of time to consumers," and that the "vacuums are incapable of reaching the advertised tank capacities." (Id. ¶¶ 37, 47.) Plaintiffs also allege that they would not have purchased the vacuums but for these misrepresentations, and that they therefore paid an unfair price [6] for their vacuums. (Id. ¶¶ 7-9, 143.) These allegations suffice to establish injury at this stage of the litigation. See *In re Hydroxycut Mktg. & Sales Practices Litig., 801 F. Supp. 2d 993, 1003 (S.D. Cal. 2011)* ("Courts have held that a plaintiff is injured and has suffered a cognizable and ascertainable loss when he receives less than what he was promised."); *In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prods. Liab. Litig., 754 F. Supp. 2d 1145, 1164 (C.D. Cal. 2010)* ("As long as plaintiffs allege a legally **[*18]** cognizable loss under the 'benefit of the bargain' or some other legal theory, they have standing.").

Plaintiffs further allege actual injury in that the vacuums did not perform as promised for their intended purpose, as they were **[*19]** unable to remove most items from the floor. (Id.) See *Koronthaly v. L'Oreal USA, Inc., 374 F. App'x 257, 259 (3d Cir. 2010)* ("Absent any allegation that [a plaintiff] received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect, [a plaintiff] has not demonstrated a concrete injury in fact."). Because all of these allegations support a finding that Plaintiffs received less than they bargained for and therefore suffered an injury-in-fact, the Court will not dismiss the second consolidated amended complaint for a lack of standing.[7]

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[5] Plaintiffs object to Defendants' motion to the extent it is brought pursuant to *Federal Rule of Civil Procedure 12(b)(1)* for lack of subject matter jurisdiction, because Defendants "fail to raise the issue of any lack of subject matter jurisdiction." (Doc. No. 107 at 19.) Accordingly, Plaintiffs contend "the Court should strike Defendants' 12(b)(1) allegations." (Id. at 20.) However, Defendants move to dismiss for lack of standing and "[a] motion to dismiss for want of standing is . . . properly brought pursuant to *Rule 12(b)(1)*, because standing is a jurisdictional matter." See *In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 243 (3d Cir. 2012)*.

[6] In their brief in support of their motion to dismiss, Defendants argue that Plaintiffs' damages are based on a speculative price inflation theory that does not constitute an injury in fact. In support of their argument, Defendants refer to *Prohias v. Pfizer, Inc., 485 F. Supp. 2d 1329, 1337 (S.D. Fla. 2007)*. However, in Prohias, the plaintiffs continued to purchase Lipitor despite their allegations that Pfizer misrepresented the drug's coronary benefits. See *id. at 1336* ("[T]he fact that [the plaintiffs] currently take Lipitor, in light of the information they have, requires me to conclude that they take Lipitor for its cholesterol-reduction or other undisputed health benefits, and therefore cannot claim to have suffered any damage from the allegedly misleading statements about Lipitor's coronary benefits."). Here, however, Plaintiffs have alleged that they would not have purchased their vacuums but for the alleged misrepresentations. (Doc. No. 97 ¶ 143.)

[7] Defendants argue that Plaintiffs cannot assert that they would have purchased a different vacuum because Shop-

D. Breach of express warranty

Defendants move to dismiss Plaintiffs' breach of express warranty claims in Count Three on the grounds that (1) the SCAC does not challenge Defendants' peak horsepower and tank capacity representation as false because the representations are literally true, and (2) Plaintiffs' fail to allege that they provided notice of the breach as required by *UCC § 2-607*. The Court will address these arguments in turn.

1. Representations were not false

To state a claim for breach of express warranty, a plaintiff must allege that: (1) the defendant made an affirmation of fact or description of its goods; (2) the statement formed part of the basis of the bargain between the parties; and (3) the product failed to conform with the affirmation or description. *U.C.C. § 2-313*. "[O]nce the buyer has become aware of the affirmation of fact or promise, the statements are presumed to be part of the 'basis of the bargain' **[*21]** unless the defendant, by 'clear affirmative proof,' shows that the buyer knew that the affirmation of fact or promise was untrue." *Cipollone v. Liggett Grp., Inc., 893 F.2d 541, 568 (3d Cir. 1990)* rev'd in part on other grounds, *505 U.S. 504, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992)*. "Whether a given statement constitutes an express warranty is normally a question of fact for the jury." *Snyder v. Farnam Cos., Inc., 792 F. Supp. 2d 712, 721-22 (D.N.J. 2011)*.

The Court finds that Plaintiffs have adequately alleged breach of an express warranty. As discussed above, they allege they purchased vacuums that made specific representations regarding peak horsepower and tank capacity, that these representations were false, and that these misrepresentations were the basis of the bargain because they would not have purchased the machines if not for the representations on the label. See *Stewart v. Smart Balance, Inc., No. 11-6174, 2012 U.S. Dist. LEXIS 138454, 2012 WL 4168584, at *12 (D.N.J. June 26, 2012)* ("[T]he Court concludes that Plaintiffs state a claim for breach of express warranty because they sufficiently allege: (1) the Defendant makes a specific description that the product is "fat free;" (2) the description was the basis of the bargain for the product; **[*22]** and (3) the product ultimately did not conform to the description because it contained one gram of fat per serving.")

Defendants argue that the claims should be dismissed because Plaintiffs "never challenge Shop-Vac's actual representations of fact as untrue." (Doc. No. 103 at 28.) Stated another way, Defendants contend that Plaintiffs do not allege breach of an express warranty because the representations regarding "peak horsepower" and tank capacity are technically true; for example, "peak horsepower," according to Defendants, is a term of art that only refers to horsepower levels reached for a brief time in laboratory conditions, not during actual consumer use, and that this use of the term on the packaging is therefore true and standard in the industry. (Id. at 23-26.)

On a motion to dismiss, however, the Court must "accept all allegations of fact as true and draw all reasonable inferences in [plaintiffs'] favor." See *Oshiver v. Levin, Fishbein, Sedran & Berman, 38 F.3d 1380, 1391 (3d Cir. 1994)*. Here, Plaintiffs allege Defendants made certain representations regarding "peak horsepower" and tank size (Doc. No. 97 ¶¶ 7-9), that Plaintiffs bought the vacuums as a result of those representations **[*23]** (id. ¶ 149), and that the representations were false and the products failed to conform with the description on the labels. (Id. ¶¶ 37, 47.) Defendants' position, that its representations were technically true, relies on information outside the pleadings,[8] such as Defendants' proffered packaging (of

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Vac's competitors also use peak horsepower ratings. (See Doc. No. 103 at 21-22, 33.) Defendants contend that the peak horsepower is simply a "data point" in that it is a "representation that compares to other competitive units in this industry." (Doc. No. 114 at 9-11.) However, Plaintiffs' SCAC supports a finding that the stated peak horsepower can be misleading regardless of whether it is an industry-wide phenomenon. For example, Plaintiffs have alleged that a vacuum with a stated **[*20]** peak horsepower of 3.5 can create more power with a full load than a vacuum with a stated peak horsepower of 5.5. (Doc. No. 97 ¶ 35.) Thus, the SCAC supports a finding that Shop-Vac's representations do not provide a helpful data point for comparison with other vacuums.

[8] For example, Defendants assert that earlier iterations of this MDL complaint expressly noted that the "peak horsepower" representations were technically true in a laboratory setting. (See Doc. No. 103 at 25-26.; Doc. No. 109 at 29 n.20.) However, "an amended complaint **[*24]** supersedes the original complaint, and facts that are neither repeated nor otherwise incorporated into the amended complaint no longer bind the pleader." *W. Run Student Hous. Associates, LLC v. Huntington Nat. Bank, 712 F.3d 165, 171-72 (3d Cir. 2013)* (quoting *188 LLC v. Trinity Indus., Inc., 300 F.3d 730, 736 (7th Cir. 2002)*. Stated another way, "[w]hen a party has amended a pleading, allegations and statements in earlier pleadings are

which the Court declines to take judicial notice), and the Court finds it would not be proper to consider them at the motion to dismiss stage. See *Smajlaj v. Campbell Soup Co., 782 F. Supp. 2d 84, 103 (D.N.J. 2011)* (denying motion to dismiss express warranty claim where "Defendants' argument as to the accuracy of the labels assumes facts not pleaded or relied upon in the Amended Complaint."). Accordingly, because a determination of whether Defendants' products actually conformed with their description is not proper at the motion to dismiss stage, the Court will deny the motion to dismiss the breach of express warranty claims.

2. Notice of breach

Defendants also argue that the breach of warranty claims should be dismissed because Plaintiffs Harbut, Reid and McMichael did not provide adequate notice of the breach prior to the initiation of the lawsuit. (Doc. No. 103 at 28-30.) *Section 2-607 of the UCC* provides that, "[w]here a tender has been accepted . . . the buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." *U.C.C. 2-607(3)(a)*. "The notification . . . need only be such as informs the seller that the transaction is claimed to involve a breach, and thus opens the way for **[*25]** normal settlement through negotiation." Id. cmt. 4. Generally, the notice must be both timely and sufficient under the circumstances and is governed by the buyer's obligation to act in good faith. *Royal Typewriter Co., a Div. of Litton Bus. Sys., Inc. v. Xerographic Supplies Corp., 719 F.2d 1092, 1102 (11th Cir. 1983)*. Where the buyer gives some notice of the breach, the issues of timeliness and sufficiency are questions of fact. Id.

The Court disagrees with Defendants and finds that Plaintiffs Harbut and Reid adequately allege that they provided notice of the breach. First, Harbut alleges he returned to the Lowe's store where he made his purchase to complain about its performance, thereby giving notice to the seller of the problematic transaction. (Doc. No. 97 ¶ 7.) Defendants essentially ask the Court to conclude that, as a matter of law, this form of notice is inadequate. (Doc. No. 103 at 30.) However, as Harbut alleges he provided some notice prior to initiation of the suit, whether or not that notice is adequate is a question of fact that the Court cannot determine on a motion to dismiss. See id. Second, Defendants similarly ask the Court to conclude that Reid's alleged notice — **[*26]** in letter to Shop-Vac sent ten days prior to initiation of the suit (Doc. No. 97 ¶ 9.) — was too close to the filing of the complaint to be considered sufficient or in good faith. (Doc. No. 103 at 29-30.) However, as with Harbut, Reid alleges he provided notice prior to filing suit, and whether that notice was sufficient or was, as Defendants argue, "sham notice," (id. at 30) is a question of fact not suited for resolution on a motion to dismiss.[9] Accordingly, the Court will not dismiss the warranty claims as to Harbut and Reid.

However, the third named Plaintiff, McMichael, does not allege he gave any notice to Defendants prior to the filing of the complaint. Rather, he alleges he provided notice on August 13, 2013, after initiation of the lawsuit and after the Court granted the initial motion to dismiss. (Doc. No. 97 **[*27]** ¶ 7.) Plaintiffs again argue that (1) the filing of the complaint can be sufficient notice under the UCC where there is no showing of prejudice, and (2) that Defendants can be charged with constructive notice of the problem by virtue of the notice provided by other Plaintiffs. (Doc. No. 107 at 43-46.) However, the Court examined and rejected these arguments in granting Defendants' first motion to dismiss. (See Doc. No. 94.) First, the Court found that "permitting the filing of the complaint to serve as notice of an alleged defect [on a warranty claim] would obviate the need for the notice requirement." (Id. at 12.) Second, the Court rejected Plaintiffs' position that constructive notice is adequate, finding that general awareness of a defect by Defendants is insufficient because "the notice requirements of *Section 2-607(3)* . . . require notice of an alleged defect with respect to a plaintiff's actual transaction." (Id.) Because the Court has already ruled on these issues, it will not address them a second time.[10] (See id.) Therefore, the Court will dismiss

not considered judicial admissions." Id. (quoting *Huey v. Honeywell, Inc., 82 F.3d 327, 333 (9th Cir. 1996)*.

[9] "Where more than one inference may be drawn from undisputed facts, or the facts are disputed, the timeliness and sufficiency of a notice of breach of warranty are questions for the jury to resolve. The question of reasonableness must be determined from the circumstances in the individual case." *Pritchard v. Liggett & Myers Tobacco Co., 295 F.2d 292, 298 (3d Cir. 1961)*.

[10] The Court is also not persuaded by Plaintiffs' argument that under Pennsylvania law, which Plaintiff asserts "may apply to [McMichael's] claims," a civil complaint can serve as notice of a breach of warranty. (Doc. No. 107 at 43.) See, e.g., *Schmidt v. Ford Motor Co., 972 F. Supp. 2d 712, 718 (E.D. Pa. 2013)* (finding that under Pennsylvania law, a "plaintiff, specifically a buyer, must provide notification of the alleged product defect to the manufacturer prior to bringing suit on a breach-of-

McMichael's warranty claims for failure to allege that he provided independent notice of the breach prior to initiation of the **[*28]** litigation.[11] See *Cohen v. Implant Innovations, Inc., 259 F.R.D. 617, 642 (S.D. Fla. 2008)*.

E. Breach of implied warranty

Defendants also move to dismiss Plaintiffs' breach of implied warranty claims for failure to state a claim. (Doc. No. 69 at 46-51.) Under *Section 2-314 of the Uniform Commercial Code*, there is an implied warranty "that the goods shall be merchantable . . . if the seller is a merchant with respect to goods of that kind." *U.C.C. § 2-314(1)*. Under the UCC, goods are merchantable if they:

> (a) pass without objection in the trade under the contract description; and
>
> (b) in the case of fungible goods, are **[*30]** of fair average quality within the description; and
> (c) are fit for the ordinary purposes for which such goods are used; and
> (d) run, within the variations permitted by the agreement, of even kind, quality and quantity within each unit and among all units involved; and
> (e) are adequately contained, packaged, and labeled as the agreement may require; and
> (f) conform to the promises or affirmations of fact made on the container or label if any.

U.C.C. § 2-314(2).

The Court finds that Plaintiffs have adequately stated a claim for a breach of the implied warranty of merchantability. As to whether the vacuums were "fit for their ordinary purposes," Plaintiff alleges that, among other problems, "the suction of the vacuum was insufficient to pick up screws, metal droppings, or drywall dust, and was not able to entirely remove saw dust from a plywood surface," "was unable to remove cat hair from sofas and furniture," and "struggled to pick up or clean up debris or liquid as expected or represented." (Doc No. 97 ¶¶ 7-9.)

In response, Defendant highlights Plaintiffs' use of phrases like "not able to entirely remove" in support of their position that it is clear from the face of complaint that the Shop-Vac **[*31]** products operated as functional vacuums and were therefore "fit for their ordinary purpose" of vacuuming. (Doc. No. 103 at 32-33.) But taking Plaintiffs allegations as true, the Court is in no position to make that determination at the motion to dismiss stage. See *In re Ford Motor Co. E-350 Van Products Liab. Litig. (No. II), No. 03-4558, 2008 U.S. Dist. LEXIS 73690, 2008 WL 4126264, at *14 (D.N.J. Sept. 2, 2008)* (denying motion to dismiss implied warranty claim because "whether a vast majority of Ford E350s did what they were supposed to do for as long as they were supposed to do it — i.e., whether they were fit for their ordinary purpose — remains an open question which this Court cannot determine on a motion to dismiss, especially where [Plaintiff] does not concede merchantability").

Moreover, Plaintiffs allege that the vacuums that they purchased did not conform to the affirmations made on the box regarding horsepower and tank capacity. (See Doc. No. 97 ¶¶ 7-9, 18, 24, 37, 46.) Accordingly, Plaintiffs have alleged facts sufficient to support a finding that the vacuums did not "conform to the promises or affirmations of fact made on the container," and thus were not merchantable under *U.C.C. § 2-314(2)*. Because **[*32]** Plaintiffs allege the vacuums failed to function properly, failed to conform to the representations on the container, and therefore failed to pass without objection in the trade, the Court will deny the motion to dismiss the implied warranty claims of named Plaintiffs Reid and Harbut. However, because the same notice requirements apply here as to the express warranty claim, McMichael's implied warranty claim will be dismissed for failure to allege that he provided proper notice.

F. Magnuson-Moss Warranty Act

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warranty theory"). The *Schmidt* court also concluded that "actual or constructive notice of the defect on the part of the manufacturer is irrelevant; the plaintiff must provide notification independently." Id.

[11] At oral argument, Plaintiffs also argued that although they did not allege McMichael provided notice prior to initiation of the lawsuit, they do allege he provided notice on August 13, 2013, after the motion to dismiss was granted and therefore prior to the filing of the operative SCAC. (See Doc. No. 114 at 18.) The Court finds that this also does not constitute notice. Permitting a Plaintiff to **[*29]** provide notice after litigation has begun as McMichael has done would, as the Court found in the initial motion to dismiss, "obviate the need for the notice requirement" and the rule's purpose of "allow[ing] the seller an opportunity to either cure the defect or settle the dispute prior to the initiation of a lawsuit." (See Doc. No. 94 at 12-13); *In re Ford Motor Co. E-350 Van Products Liab. Litig. (No. II), No. 03-cv-4558, 2008 U.S. Dist. LEXIS 73690, 2008 WL 4126264, at *10 (D.N.J. Sept. 2, 2008)* ("[W]here a plaintiff alleges no pre-litigation notice at all, the issue of the notice's sufficiency is moot and appropriately can be decided as a matter of law at this stage.") (emphasis added).

Defendants also move to dismiss Plaintiffs' implied and express warranty claims under the Magnuson-Moss Warranty Act (MMWA). Under the MMWA, *15 U.S.C. § 2310(d)(1)*, "a consumer who is damaged by the failure of a supplier, warrantor, or service contractor to comply with any obligation under this chapter, or under a written warranty, implied warranty, or service contract, may bring suit for damages and other legal and equitable relief." Regarding warranty claims under the MMWA, "this court's disposition of the state law warranty claims determines the disposition of the Magnuson-Moss Act claims."[12] *Clemens v. DaimlerChrysler Corp., 534 F.3d 1017, 1022 (9th Cir. 2008)*; see also *Cooper v. Samsung Elecs. Am., Inc., 374 Fed. App'x 250, 254 (3d Cir. 2010)* **[*33]** ("In the instant case, [plaintiff's] Magnuson-Moss claim is based upon his state law claims of breach of express and implied warranties. Since the District Court correctly dismissed both of those claims, [plaintiff's] Magnuson-Moss claim was also properly dismissed."). Thus, because the Court will allow named Plaintiffs Harbut and Reid's state law-based warranty claims to go forward, their MMWA warranty claims must similarly proceed. However, because Plaintiff McMichael failed to properly plead a breach of warranty claim under state law, he cannot maintain his MMWA warranty claim, and it will be dismissed.[13]

Plaintiffs additionally argue that their MMWA express warranty claims are not based on state law, but rather constitute an independent MMWA express written warranty violation. (Doc. No. 107 at 32-33.) The MMWA defines a written warranty as:

> any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship is defect free or will meet a specified level of performance over a specified period of time.

15 U.S.C.A. § 2301(6)(A) (emphasis added). Defendants argue that Plaintiffs have not alleged beyond conclusory labels that Defendants promised a defect-free product or a certain level of performance over a specific time period. (Doc. No. 103 at 27-29.) Plaintiffs argue that they have alleged independent MMWA express warranty claims based on (1) the **[*35]** failure of the vacuums to meet the power and capacity representations (Doc. No. 107 at 31), and (2) a three-year written home use warranty included on the machines' parts list (id. at 32).

To the extent Plaintiffs' independent MMWA express warranty claim is premised on the allegedly fraudulent representations regarding horsepower and tank capacity, the Court finds that Plaintiffs do not state a claim. The alleged misrepresentations regarding peak horsepower and tank capacity constitute descriptions of the product, not promises that the product will be "defect free" under the MMWA. See *Jones v. ConAgra Foods, Inc., 912 F. Supp. 2d 889, 903-04 (N.D. Cal. 2012)* (dismissing MMWA claim and finding that mere product descriptions do not constitute a promise that a product is "defect free").

Additionally, although Plaintiffs state in their complaint that "Defendants have . . . made written affirmations of fact or promises that the vacuums would meet a specified level of performance over a specified period of time" (Doc. No. 97 ¶ 33), the SCAC does not specify any such promises or warranties and a court "need not credit a complaint's 'bald assertions' or 'legal conclusions' when deciding a motion **[*36]** to dismiss." *Morse v. Lower Merion Sch. Dist. 132 F.3d 902, 906 (3d Cir. 1997)*. However, in their brief in opposition to the motion to dismiss, Plaintiffs now argue that their MMWA express warranty claim is premised on a three-year written warranty allegedly included with the machines, a scan of which they included as an exhibit attached to their brief in opposition to the motion to dismiss as Exhibit A. (Doc No. 107 at 32, 53.) Critically, Plaintiffs did not refer to this alleged three-year written warranty anywhere in the SCAC and did not attach this warranty as an exhibit to the SCAC. Plaintiffs cannot amend their complaint through a brief in opposition to a motion to dismiss. See *Car Carriers, Inc. v. Ford Motor Co., 745*

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[12] Defendants do not dispute this point, and acknowledge that "except insofar as Plaintiffs can plead an independent MMWA claim based on a warranty as specifically defined in *15 U.S.C. 2301*, their MMWA claims rise or fall with their state law implied and express warranty claims." (Doc. No. 109 at 22 n.14.)

[13] Although this Court held that pre-litigation notice was not necessarily required under the MMWA (Doc. No. 94 at 8-9), Plaintiffs' MMWA warranty claims survive or fail with the state law warranty claims, and, as discussed in Section III.D.2, McMichael has not alleged a valid state **[*34]** law breach of warranty claim. See *Clemens, 534 F.3d at 1022*; see also *Schimmer v. Jaguar Cars, Inc., 384 F.3d 402, 405 (7th Cir. 2004)* ("The [MMWA] . . . allows consumers to enforce written and implied warranties in federal court, borrowing state law causes of action.")

F.2d 1101, 1107 (7th Cir. 1984), cert. denied, 470 U.S. 1054, 105 S. Ct. 1758, 84 L. Ed. 2d 821 (1984) ("It is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss."). Because Plaintiffs have not alleged in their SCAC beyond conclusory averments that Defendants made a written affirmation of fact or promise that the vacuums are "defect free" or "will meet a specified level of performance over a specified period of time," the Court finds Plaintiffs have **[*37]** not alleged an independent MMWA claim based on an express written warranty. Accordingly, although Plaintiffs Harbut and Reid's MMWA claims may proceed based on the valid underlying state law causes of action, Plaintiff McMichael's MMWA claim will be dismissed.

G. Consumer fraud claims

Lastly, Defendants move to dismiss Plaintiffs' claims under state consumer protection statutes for deceptive and unfair trade practices on the grounds that (1) no reasonable consumer could have been misled by the representations because Plaintiffs' expectations were unreasonable as a matter of law, (2) Plaintiffs do not allege actual injury, and (3) to the extent Plaintiffs allege unfair business practices in violation of state consumer fraud statutes, Plaintiffs do not actually allege unfair conduct by Defendants. (Doc. No. 103 at 38-42.) Regarding Defendants' second argument, the Court has already found Plaintiffs have alleged actual injury.[14] See supra Part III.C. Thus, the only arguments the Court still needs to address are whether Plaintiffs' expectations were unreasonable as a matter of law, and whether Plaintiffs allege unfair business practices by Defendants.

First, the Court will address Defendants' contention that the claims should be dismissed because no reasonable consumer could have been misled by the alleged misrepresentations. Under the reasonable consumer standard, "if no reasonable consumer would be misled, then the allegations may also be dismissed as a matter of law." Haskell v. Time, Inc., 857 F. Supp. 1392, 1399 (E.D. Cal. 1994). The crux of Defendants' argument is that the horsepower expected by Plaintiffs is impossible in actual use, and therefore "reasonable consumers could not reasonably be deceived into believing that 'peak horsepower' means they were purchasing a vacuum that produces 'operational horsepower' at levels that do not exist." (Doc. No. 103 at 39-40.) Additionally, Defendants contend that "peak horsepower" is an essentially meaningless term to a reasonable consumer. (Id. at 40 n.12)

In the Court's order dismissing the original complaint, it noted that because it was dismissing the complaint due **[*39]** to a lack of specificity in the pleading, it declined to address Defendants' argument that Plaintiffs' expectations were unreasonable as a matter of law. (Doc. No. 94 at 17.) However, the Court cautioned in its order that "only in the clearest of cases is it proper for a court to make a determination that a reasonable consumer is not likely to be misled at the motion to dismiss stage."[15] (Id.) Here, Defendants' argument presupposes a rather heightened awareness by consumers of what constitutes achievable horsepower levels for a vacuum. Consistent with its warning in the initial order, the Court finds that it cannot conclude at this stage that a reasonable consumer would not understand the term "peak horsepower" to mean horsepower achieved in actual use of the vacuum. Accordingly, because this is not the rare occasion in which the Court can resolve this question at the motion to dismiss stage, it will not dismiss the consumer fraud claims on the basis that no reasonable consumer would be misled by Defendants' alleged misrepresentations.

Further, the Court disagrees with Defendants' contention that Plaintiffs do not allege unfair behavior, which Defendants define as conduct that "offends public policy; is immoral, unethical, oppressive or unscrupulous; or causes substantial injury." (Doc. No. 103 at 42.) Essentially, Defendants assert that the SCAC's allegations cannot amount to unfair conduct, because Plaintiffs "do not even allege that Shop-Vac's peak horsepower and tank size representations are untrue." (Id.) In other words, Defendants argue that they accurately disclosed the peak horsepower and tank size

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[14] See also Ivie v. Kraft Foods Global, Inc., 961 F. Supp. 2d 1033, 1045-46 (N.D. Cal. 2013) **[*38]** ("The alleged purchase of a product that plaintiff would not otherwise have purchased but for the alleged unlawful label is sufficient to establish an economic injury-in-fact for plaintiff's unfair competition claims.").

[15] See Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc., 653 F.3d 241, 252 (3d Cir. 2011) (holding that no reasonable consumer could be misled as to the **[*40]** origin of Bacardi's "Havana Club" rum, where the bottle prominently features the phrase "Puerto Rican Rum"); cf. F.T.C. v. Cantkier, 767 F. Supp. 2d 147, 159 (D.D.C. 2011) ("Whether or not Lady's ads and websites, taken in their full context, were 'likely to mislead consumers acting reasonably under the circumstances' is ultimately a factual question that cannot be resolved at the motion to dismiss stage.").

of their vacuums. (Id.) As discussed in Section III.B.1, in ruling on Defendants' motion to dismiss, the Court must accept Plaintiffs' factual allegations as true, and the Court finds that Plaintiffs have adequately **[*41]** alleged that the machines do not comport with the horsepower and tank capacity representations. Because the factual issue of whether Defendants accurately disclosed the horsepower and tank size of their vacuums is not properly determined at this stage, the Court will deny the motion to dismiss Plaintiffs' consumer fraud claims on this ground as well.

IV. CONCLUSION

The Court will deny Defendants' motion to dismiss the breach of express and implied warranty claims brought by named Plaintiffs Hubert and Reid. However, the Court finds the third named Plaintiff, McMichael, has not adequately alleged actionable breach of express and implied warranty claims, and will dismiss his warranty claims. Similarly, while the Court will not dismiss the Magnuson-Moss Warranty Act claims brought by Plaintiffs Hubert and Reid, to the extent Plaintiff McMichael brings a MMWA claim, it will be dismissed. Lastly, the Court will not dismiss any of the consumer fraud claims. An order consistent with this memorandum follows.

ORDER

AND NOW, on this 17th day of July 2014, **IT IS HEREBY ORDERED THAT** Defendants' motion to dismiss (Doc. No. 102) is **GRANTED IN PART** and **DENIED IN PART** as follows:

1. Plaintiff Alan McMichael's **[*42]** claims alleging breach of express and implied warranties are **DISMISSED WITH PREJUDICE;**
2. Plaintiffs Andrew Harbut and Kris Reid's claims alleging breach of express and implied warranties are not dismissed;

3. Plaintiff Alan McMichael's claim alleging violations of the Magnuson-Moss Warranty Act is **DISMISSED WITH PREJUDICE**;
4. Plaintiffs Andrew Harbut and Kris Reid's claims alleging violations of the Magnuson-Moss Warranty Act are not dismissed;
5. Plaintiffs' claims alleging violations of state consumer fraud laws are not dismissed; and
6. The Courtroom Deputy is directed to contact counsel in order to schedule an upcoming status conference.

/s/ Yvette Kane

Yvette Kane, District Judge

United States District Court

Middle District of Pennsylvania

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JHE, Inc. v. SEPTA

Common Pleas Court of Philadelphia County, Pennsylvania, Civil Trial Division

May 17, 2002, Decided

No. 1790, Commerce Program, Control Nos. 010312 and 020586

Reporter
2002 Phila. Ct. Com. Pl. LEXIS 78 *; 2002 WL 1018941

JHE, INCORPORATED, Plaintiff v. SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY, Defendant

Judges: [*1] ALBERT W. SHEPPARD, JR., J.

Opinion by: ALBERT W. SHEPPARD, JR.

Opinion

OPINION

Albert W. Sheppard, Jr., J.

Defendant, Southeastern Pennsylvania Transportation Authority ("SEPTA"), has filed Preliminary Objections to the Complaint ("Complaint") of plaintiff, JHE, Incorporated ("JHE"). In response JHE has filed Preliminary Objections to the Preliminary Objections.

For the reasons set forth, JHE's Preliminary Objections are overruled, and SEPTA's Preliminary Objections are sustained, in part, and overruled, in part.

BACKGROUND

In September 1997, SEPTA awarded a general construction contract for renovations to its Overbrook Station ("Project") to Craft Century Construction, Inc. ("CCC"). SEPTA terminated its contract with CCC in April 1998 after design, production and management difficulties arose. Three months later, CCC's bonding company requested quotations to complete the Project, and JHE was awarded the Project contract in December 1998.

Of the four parallel tracks that traverse SEPTA's Overbrook Station ("Station"), the outer two are owned by SEPTA, and the inner two are owned by that National [*2] Railroad Passenger Corp. ("Amtrak"). As part of the construction contract between JHE and SEPTA ("Contract"), JHE agreed that any work to be performed within 15 feet of the Amtrak-owned tracks ("Amtrak Tracks") required the presence of an Amtrak safety flagperson. However, the Complaint alleges that SEPTA later unilaterally expanded this exclusion zone from 15 feet to 25 feet. This expansion, along with SEPTA-mandated complete track outages in lieu of flagperson protection, allegedly caused JHE to incur significant cost increases and resulted in numerous time delays. Allegedly, SEPTA also pushed for early opening of a pedestrian tunnel requiring extra work outside the scope of the contract, and failed to provide proper plans and specifications. Finally, after SEPTA's demands allegedly made work on the Project impracticable, SEPTA terminated the Contract on October 5, 2001.

Within this context, JHE brought suit for breach of contract, violations of the Pennsylvania Public Works Bond Payment Act ("PWBPA"), [1] breach of contract/cardinal change, estoppel, breach of implied duty of good faith and fair dealing, negligent misrepresentation and fraudulent misrepresentation. SEPTA [*3] filed comprehensive Preliminary Objections ("SEPTA's Objections"), which include a novel question regarding the implied covenant of good faith and fair dealing and the defense of sovereign immunity.

JHE countered with its own set of Preliminary Objections ("JHE's Objections") asserting that the affirmative defense of sovereign immunity may not be raised by way of preliminary objections.

DISCUSSION

This court holds that JHE may not raise an alleged breach of an implied covenant of good faith and fair dealing as a separate count and that this claim (Count V) must be dismissed. Further, three additional counts -- Count II (Pennsylvania Public Works Bond Payment Act); Count VI (Negligent Misrepresentation), Count VII (Fraudulent Misrepresentation) -- are dismissed. Also,

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[1] 62 Pa. C.S. § 3931-3939.

certain portions of the Complaint are either insufficiently specific or scandalous and impertinent and are stricken.

Pennsylvania Rule of Civil Procedure 1030(a) generally [*4] requires that affirmative defenses, including the affirmative defense of sovereign immunity, be pled as a new matter and not raised in preliminary objections. *Heifetz v. Philadelphia State Hosp.,* 482 Pa. 386, 390 n.5, 393 A.2d 1160, 1162 n.5 (1978); *CSX Transp., Inc. v. Franty Constr.,* 157 Pa. Commw. 620, 623 n.1, 630 A.2d 932, 934 n.1 (1993). This supports JHE's assertion that SEPTA's attempt to raise sovereign immunity in its Objections is improper.

SEPTA counters that in *Caplen v. Burcik,* 2000 Phila. Ct. Com. Pl. LEXIS 52, No. 3144, 2000 WL 33711068 (Pa. Com. Pl. Aug. 4, 2000), this Court recognized that "sovereign immunity may be raised by preliminary objection where it is apparent on the face of the pleadings or where the plaintiff has not objected to this procedure, despite that immunity is an affirmative defense which normally should be pleaded as new matter in accordance with Pa.R.C.P. 1030." [*5] 2000 Phila. Ct. Com. Pl. LEXIS 52, 2000 WL 33711068, at *9. *See also E-Z Parks, Inc. v. Larson,* 91 Pa. Commw. 600, 608, 498 A.2d 1364, 1369 (1985), *aff'd,* 509 Pa. 496, 503 A.2d 931 (1986) (noting that a court may "address an immunity issue on preliminary objections where the immunity is apparent on the face of the pleadings, or where the plaintiff has not objected to the use of preliminary objections in its answer or any other pleading"); *Potts v. Davis,* 149 Pa. Commw. 8, 11, 610 A.2d 74, 75 (1990) ("Preliminary objections are a proper vehicle for raising the defense of sovereign immunity where, as here, the defense is apparent on the face of the pleading under attack"); *Poliskiewicz v. East Stroudsburg Univ.,* 113 Pa. Commw. 13, 15 n.1, 536 A.2d 472, 473 n.1 (1988) ("Preliminary objections are a proper vehicle for raising the defense of sovereign immunity where, as here, the defense is apparent on the face of the pleading under attack."). *Cf.* [*6] *Malia v. Monchak,* 116 Pa. Commw. 484, 489, 543 A.2d 184, 187 (1988) ("If the defense of immunity is apparent on the face of the challenged pleading, the defense of immunity will be considered on preliminary objection unless the opposing party challenges this procedure by filing preliminary objections to the preliminary objections.").

This court finds SEPTA's argument persuasive. Thus, the court may address and sustain SEPTA's Objections asserting sovereign immunity if this defect is apparent from the face of the Complaint. JHE's Objections are, therefore overruled.

II. SEPTA's Objections Asserting Legal Insufficiency Are Sustained in Part and Overruled in Part

A review of the Complaint reveals that Count II - - Pennsylvania Public Works Bond Payment Act, Count V - - Breach of Implied Duty of Good Faith and Fair Dealing, Count VI - - Negligent Misrepresentation and Count VII - - Fraudulent Misrepresentation are legally insufficient and must be dismissed. Additionally, JHE is not entitled to an award of punitive damages, although it may proceed on its remaining contract-related claims.

A. JHE's Claim for Violations of the PWBPA Is Legally Insufficient

[*7] Under 62 Pa. C.S. § 3932, a "government agency shall pay the contractor or design professional strictly in accordance with the contract." However, this provision does not apply to "[a] transportation authority organized or operating under 74 Pa.C.S. Ch. 17 (relating to metropolitan transportation authorities)." 62 Pa. C.S. § 3938(b)(5). Our Commonwealth Court has held that SEPTA meets the definition of an entity operating under this chapter. *Warrick v. Pro Cor Ambulance, Inc.,* 709 A.2d 422, 425 (Pa. Commw. Ct. 1997), *aff'd,* 559 Pa. 44, 739 A.2d 127 (1999). Accordingly, the PWBPA does not apply to SEPTA, and Count II, which asserts violations of the PWBPA, must be dismissed.

B. The Objections to Count III Are Overruled

The doctrine of cardinal change has been applied in a construction contract context and articulated as follows:

> It is well-settled that a cardinal change occurs when the government effects an alteration in the work so drastic that it effectively requires the contractor to perform duties materially different from those originally [*8] bargained for. Consequently, a plaintiff has no right to complain if the project it ultimately constructed was essentially the same as the one it contracted to construct. This doctrine is created to provide a breach remedy for contractors who are directed by the government to perform work which is not within the general scope of the contract and exceeds the scope of the contract's changes clause. A modification generally falls within the scope of the original procurement if potential bidders would have expected it to fall within the contract's changes clause. The government cannot impose obligations on a contractor which far exceed those contemplated in

> their contract.
>
> Cases that have found cardinal changes have involved changes that altered the nature of the thing constructed. Each case must be analyzed on its own facts and in light of its own circumstances, giving just consideration to the magnitude and quality of the changes ordered and their cumulative effect upon the project as a whole. Moreover, the contractor must prove facts with specificity that support its allegations that a cardinal change occurred.

[*9]

PCL Constr. Servs., Inc. v. United States, 47 Fed. Cl. 745, 804 (2000) (citations, quotation marks and brackets omitted). This doctrine is used almost exclusively by contractors suing government entities and has been applied by Pennsylvania courts. *See, e.g., Roy F. Weston Servs., Inc. v. Halliburton NUS Envtl. Corp.,* 1993 U.S. Dist. LEXIS 2841, No. Civ. A. 91-1133, 1993 WL 57182 (E.D. Pa. Mar. 3, 1993).

It appears that courts treat the cardinal change doctrine as a vehicle for contract interpretation, not as a separate claim:

> Under the contract doctrine of "cardinal" changes that where a party to a contract alters the terms of the other party's performance to such an extent that the alterations could not have been within the realm of the parties contemplation as evidenced by the parties' written agreement, the other party may elect not to perform and hold the other party *liable for breach of contract.*

Fuller Co. v. Brown Minneapolis Tank & Fabricating Co., 678 F. Supp. 506, 509 (E.D. Pa. 1987) (emphasis added). However, ignoring for a moment how Count III is titled, it appears that JHE [*10] intends for Count III to serve as an equitable claim in the event that the Contract between the parties is found to be invalid due to SEPTA's modifications. *See* Pl. Mem. 11 ("When a party is subjected to a cardinal change in its contract, the change is such to affect [sic] a repudiation of that contract. The party is then able to seek damages either in quantum meruit or quasi contract."). [2] In situations like this, "Pennsylvania courts faced with a conflict between the allegations of a count and the count's title look at the allegations and not the title." *Thermacon Enviro Sys., Inc. v. GMH Assocs. of Amer., Inc.,* 2001 Phila. Ct. Com. Pl. LEXIS 74, No. 4369, 2001 WL 1807890, at *3 n.1 (Pa. Com. Pl. July 18, 2001) (citing *Zernhelt v. Lehigh County Office of Children & Youth Servs.,* 659 A.2d 89 (Pa. Commw. Ct. 1995), *Maute v. Frank,* 441 Pa. Super. 401, 403-04, 657 A.2d 985, 986 (1995), and *Commonwealth ex rel. Saltzburg v. Fulcomer,* 382 Pa. Super. 422, 555 A.2d 912 (1989)). Because Count III makes out a viable claim based on quantum meruit, those Objections are overruled.

[*11] **C. JHE May Proceed on its Estoppel Claim**

Pennsylvania has adopted Restatement (Second) of Contracts Section 90(1), which states that "a promise which the promisor should reasonably expect to induce action or forbearance on the part of the promisee or a third person and which does induce such action or forbearance is binding if injustice can be avoided only by enforcement of the promise." *Thatcher's Drug Store v. Consolidated Supermarkets,* 535 Pa. 469, 476, 636 A.2d 156, 159 (1994) (brackets omitted). SEPTA asserts that the doctrine of estoppel is unavailable where the parties' relationship is founded on a written agreement or express contract. [3] Even if this is so, however, Pennsylvania Rule of Civil Procedure 1020(c) allows the presentation of claims in the alternative. *See Schreiber v. Republic Intermodal Corp.,* 473 Pa. 614, 626, 375 A.2d 1285, 1291 (1977) (Rule 1020(c) "reflect[s] the general principle that plaintiffs should not

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[2] The elements of a claim for unjust enrichment are "benefits conferred on defendant by plaintiff, appreciation of such benefits by defendant, and acceptance and retention of such benefits under such circumstances that it would be inequitable for defendant to retain the benefit without payment of value." *Wiernik v. PHH U.S. Mortgage Corp.,* 1999 PA Super 193, 736 A.2d 616, 622 (Pa. Super. Ct. 1999), *app. denied,* 561 Pa. 700, 751 A.2d 193 (2000). Similarly, an action based on the quasi-contract doctrine of quantum meruit requires that "one person has been unjustly enriched at the expense of another," and thus cannot be sustained without satisfying the elements of unjust enrichment. *Mitchell v. Moore,* 1999 PA Super 77, 729 A.2d 1200, 1202 n.2 (Pa. Super. Ct. 1999) (citation omitted).

[3] Although SEPTA does not cite any case law in support of this proposition, several cases do support this principle of law. *See, e.g., Mitchell v. Moore,* 1999 PA Super 77, 729 A.2d 1200, 1203 (Pa. Super. Ct. 1999); *Roman Mosaic & Tile Co. v. Vollrath,* 226 Pa. Super. 215, 217, 313 A.2d 305, 307 (1974). *Cf. Gee v. Eberle,* 279 Pa. Super. 101, 119, 420 A.2d 1050, 1060 (1980) (allowing plaintiffs to assert claim for unjust enrichment where they did not and could not assert any contractual right against defendant).

be forced to elect a particular theory in pursuing a claim, and avoids the attendant possibility that [*12] meritorious claims will fail because the wrong legal theory was chosen"); *Lampl v. Latkanich,* 210 Pa. Super. 83, 231 A.2d 890 (1967) (allowing plaintiff to proceed on breach of contract and unjust enrichment claims). *Cf. Peisach v. Continental Assurance Co.,* June Term, No. 3663, slip op. at 5 (Pa. Com. Pl. Jan. 8, 2002) (Herron, J.) (dismissing unjust enrichment claim where "the clear existence of a contract in the form of the Policy doubtlessly will preclude the Plaintiff from proceeding on her unjust enrichment claim"). [4]

[*13] Thus, the fact that JHE's primary claims may be predicated on a contract does not preclude it from continuing on its estoppel claim at this stage.

D. JHE's Claim for Breach of the Implied Covenant of Good Faith Is Legally Insufficient

The implied contractual covenant, or duty, of good faith is a legal concept shrouded in mystery and confusion in Pennsylvania.

After reviewing the relevant decisions, this court concludes that the implied covenant of good faith does ***not*** allow for a claim separate and distinct from a breach of contract claim. Rather, a claim arising from a breach of the covenant of good faith must be prosecuted as a breach of contract claim, as the covenant does nothing more than imply certain obligations into the contract itself.

1. JHE's Claim Against SEPTA for Breach of the Duty of Good Faith Does Not Sound in Tort

At the outset, it is important to be clear on the nature of the good faith claim that JHE is raising. As a rule, allegations of a breach of the covenant of good faith sound in contract. *See Creeger Brick & Bldg. Supply Inc. v. Mid-State Bank & Trust Co.,* 385 Pa. Super. 30, 35, 560 A.2d 151, 153 (1989) ("Where a [*14] duty of good faith arises, it arises under the law of contracts, not under the law of torts."). While other jurisdictions have recognized a tort claim for bad faith, almost exclusively in an insurance context, Pennsylvania has declined to do so. *See D'Ambrosio v. Pennsylvania National Mutual Casualty Insurance Co.,* 494 Pa. 501, 431 A.2d 966 (1981) (rejecting *Gruenberg v. Aetna Insurance Co.,* 9 Cal. 3d 566, 108 Cal. Rptr. 480, 510 P.2d 1032 (Cal. 1973), which allowed insured to bring a claim in tort against insurer for bad faith). Instead, Pennsylvania statutory law allows an action against an insurance company for bad faith conduct. 42 Pa. C.S. § 8371. Although it remains to be seen whether an action under this statute sounds in tort or contract, [5] it is clear that a bad faith action against an insurer is distinct from an action based solely on the covenant of good faith. [*15] Thus, the conclusions reached in this Opinion are limited to contract-related claims of the type brought by JHE and do not extend to "good faith" as the term may be used in other contexts.

2. Breach of the Contractual Duty of Good Faith Is Not a Claim Separate from a Breach of Contract Action

In Count V, JHE asserts an independent claim for breach of the covenant of good faith implied in the contract. Because it is clear that this is not a bad faith claim arising under § 8371, the court must focus on how a plaintiff can assert a claim arising from a breach of contract of the covenant of good faith. Thus, the court must ask the following question: is the covenant of good faith a principle of contract interpretation, making a breach of the covenant nothing more than a facet of a breach of contract [*16] claim, or does a breach of the covenant of good faith give rise to a separate cause of action that may and must be pled separately? [6]

[*17] Although there is no Pennsylvania case on this subject, courts in other jurisdictions have found that breach of the covenant of good faith is subsumed in a

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[4] Opinion available at http://courts.phila.gov/cptcvcomp.htm.

[5] For an extensive discussion on this issue, see *Trujillo v. State Farm Mutual Automobile Insurance Co.,* 54 Pa. D. & C.4th 24, 2001 WL 1807927 (Pa. Com. Pl. Dec. 6, 2001).

[6] It is important to recognize the implications of the answer to this question. The interpretation of a contract generally is an issue of law to be determined by the court. *Highmark, Inc. v. Hospital Serv. Ass'n of N.E. Pa.,* 2001 PA Super 278, 785 A.2d 93, 98 (Pa. Super. Ct. 2001); *Mellon Bank, N.A. v. National Union Ins. Co. of Pittsburgh,* 2001 PA Super 32, 768 A.2d 865, 868 (Pa. Super. Ct. 2001). In contrast, questions as to the intent of the parties and whether the contract has been breached are questions of fact often reserved for a jury. *GMH Associates, Inc. v. Prudential Realty Group,* 2000 PA Super 59, 752 A.2d 889, 898 (Pa. Super. Ct. 2000). Thus, how the covenant of good faith is categorized will affect how it is treated by trial and appellate courts alike. More specifically, if the implied covenant is a rule of contract interpretation, determing what obligations the covenant involves will raise questions of law, while determining whether those ligalities have been sustained will be questions of fact.

breach of contract claim. In *Baxter Healthcare Corp. v. O.R. Concepts, Inc.,* 69 F.3d 785, 792 (7th Cir. 1995), for example, the court held that the covenant of good faith "is not an independent source of duties for the parties to a contract," but merely "guides the construction of the explicit terms in the agreement." 69 F.3d at 792 (citations and quotation marks omitted). *See also, e.g., Echo, Inc. v. Whitson Co.,* 121 F.3d 1099, 1106 (7th Cir. 1997) ("The obligation of good faith . . . creates neither a cause of action sounding in tort nor its own sui generis cause of action."); *Medtronic, Inc. v. ConvaCare, Inc.,* 17 F.3d 252, 256 (8th Cir. 1994) ("Minnesota law does not recognize a cause of action for breach of the implied covenant of good faith and fair dealing separate from the underlying breach of contract claim."); [*18] *Designers N. Carpet, Inc. v. Mohawk Indus., Inc.,* 153 F. Supp. 2d 193, 196 (E.D.N.Y. 2001) ("A claim for breach of an implied covenant of good faith and fair dealing does not provide a cause of action that is separate and different from a breach of contract claim. Rather, breach of that duty is merely a breach of the underlying contract."); *Adams v. NVR Homes, Inc.,* 135 F. Supp. 2d 675, 699 (D. Md. 2001) ('[A] plaintiff seeking a recovery for breach of contract may not in Maryland assert a separate claim for breach of the covenant of good faith and fair dealing implied in that contract."). [7]

[*19] This court suggests that the analysis of Pennsylvania law undertaken in *McHale v. NuEnergy Group,* 2002 U.S. Dist. LEXIS 3307, No. Civ. A. 01-4111, 2002 WL 321797, (E.D. Pa. Feb. 27, 2002), is particularly insightful:

> Plaintiffs' claim for breach of the covenant of good faith and fair dealing must be dismissed. This court finds that Pennsylvania law would not recognize a claim for breach of covenant of good faith and fair dealing as an independent cause of action separate from the breach of contract claim since the actions forming the basis of the breach of contract claim are essentially the same as the actions forming the basis of the bad faith claim. Plaintiffs cite *Somers v. Somers,* 418 Pa. Super. 131, 613 A.2d 1211, 1213 (Pa. Super. Ct. 1992) in support of the claim for breach of implied covenant of good faith and fair dealing. However, the majority in *Somers* only stated that the general duty of good faith and fair dealing in the performance of a contract has been adopted in this Commonwealth, and that a party may bring a claim for breach of contract. A breach of such covenant is a breach of contract action, not an independent [*20] action for breach of a duty of good faith and fair dealing. Therefore, the claim for breach of covenant of good faith and fair dealing is dismissed.

2002 U.S. Dist. LEXIS 3307, 2002 WL 321797, at *8 (citations omitted). *See also Commonwealth v. BASF Corp.,* 2001 Phila. Ct. Com. Pl. LEXIS 95, No. 3127, 2001 WL 1807788, at *12 (Pa. Com. Pl. Mar. 15, 2001) ("Pennsylvania law does not allow for a separate cause of action for breach of either an express or implied duty of good faith, absent a breach of the underlying contract."). [8]

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[7] In an insurance context, where an insured brings a tort or tort-like bad faith claim against her insurer, some courts have justifiably held that these claims are distinct and separate from claims stemming from breach of the covenant of good faith. *See, e.g., Aranda v. Insurance Company of North America,* 748 S.W.2d 210, 213-14, 31 Tex. Sup. Ct. J. 279 (Tex.1988). *Cf. The Birth Center v. St. Paul Cos.,* 567 Pa. 386, 787 A.2d 376, 390 (2001) (Nigro, J.) (concurring opinion) ("I believe that the law in this Commonwealth establishes that there are two separate 'bad faith' claims that an insured can bring against an insurer-a contract claim for breach of the implied contractual duty to act in good faith, and a statutory bad faith tort claim sounding in tort under 42 Pa.C.S. § 8371.").

[8] A detailed analysis of how to plead a breach of contract claim arising from a breach of the duty of good faith was set forth in *Galileo International, L.L.C. v. Ryanair, Ltd.,* 2002 U.S. Dist. LEXIS 3317, 2002 WL 314500, *6 (N.D. Ill.), where the court examined counterclaim defendant Galileo's assertion that Ryanair's claim for breach of the covenant of good faith could not be brought as a separate action:

> Galileo is correct in that Illinois law does not permit a party to seek an independent claim for breach of the implied obligation of good faith which Illinois law incorporates into all contracts. To bring a claim for breach of the obligation of good faith, a party must include such a claim within a breach of contract claim. Where a party fails to properly plead a claim for good faith within a count for breach of contract, the court should properly dismiss the separate claim for good faith.
>
> Here, Ryanair concedes that it cannot state an independent claim for breach of good faith. However, Ryanair contends that its good faith claim is part of a count for breach of contract, and therefore is properly pled. Count IV is titled "BREACH OF CONTRACT (Obligation of good faith)" and incorporates by reference Ryanair's breach of contract claims (Counts I and II). This position is contrary to the Seventh Circuit's interpretation of Illinois law in *Echo, Inc.,* 121 F.3d at 1105-06, where

[*21] Based on this analysis, this court holds that a breach of the covenant of good faith is nothing more than a breach of contract claim and that separate causes of action cannot be maintained for each, even in the alternative. [9] Accordingly, JHE's claim for breach of the covenant of good faith in the Contract is dismissed. Because JHE's independent claim for breach of the covenant of good faith is legally insufficient, the court need not consider, at this stage, whether the relationship between the parties allows the court to imply a covenant of good faith.

[*22]

E. The Economic Loss Doctrine Bars JHE's Negligent Misrepresentation Claim

The purpose of the economic loss doctrine, as adopted in Pennsylvania, is "maintaining the separate spheres of the law of contract and tort." *New York State Elec. & Gas Corp. v. Westinghouse Elec. Corp.,* 387 Pa. Super. 537, 550, 564 A.2d 919, 925 (1989). Pennsylvania's economic loss doctrine has its origins in *R.E.M. Coal Co. v. Clark Equipment Co.,* 386 Pa. Super. 401, 563 A.2d 128 (1989). There, the court considered:

> The appropriateness of permitting recovery in tort where a product malfunctions because of an alleged defect in the product, causing damage to the product itself and consequential damages in the nature of costs of repair or replacement or lost profits, but the malfunction causes no personal injury and no injury to any other property of the plaintiff.

386 Pa. Super. at 403, 563 A.2d at 129. Ultimately, the Court concluded that "negligence and strict liability theories do not apply in an action between commercial enterprises involving a product that malfunctions where the only resulting damage is to the product [*23] itself." 386 Pa. Super. at 412-13, 563 A.2d at 134. In its current form, the Commonwealth's version of the doctrine precludes recovery for economic losses in negligence [10] and strict liability actions where the plaintiff has suffered no physical injury or property damage. *See, e.g., Moscatiello v. Pittsburgh Contractors Equip. Co.,* 407 Pa. Super. 378, 385-86, 595 A.2d 1198, 1201 (1991) ("Purely economic losses cannot be recovered where the plaintiff's action sounded solely in negligence or strict liability."); *Spivack v. Berks Ridge Corp.,* 402 Pa. Super. 73, 78, 586 A.2d 402, 405 (1990) ("The general rule of law is that economic losses may not be recovered in tort (negligence) absent physical injury or property damage.").

[*24] In the instant dispute, there is no allegation in the Complaint of any physical injury or property damage incurred by JHE. JHE's negligent misrepresentation claim does nothing more than incorporate its earlier allegations, including those iterated in its breach of contract claim. Accordingly, the economic loss doctrine bars JHE's negligent misrepresentation claim, and Count VI must be dismissed.

The opposite outcome is required for JHE's fraudulent misrepresentation claim. This Court has previously examined the cases applying the economic loss doctrine to fraudulent and intentional misrepresentation cases and held the doctrine inapplicable. *See, e.g., First Republic Bank v. Brand,* 50 Pa. D. & C.4th 329, 340-45 (Pa. Com. Pl. 2000). [11] As such, the economic loss

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the court clearly stated independent claims of breach of duty of good faith are not permitted under Illinois law.

2002 U.S. Dist. LEXIS 3317, 2002 WL 314500, at *6 (citations omitted).

[9] The implication of this conclusion is that determining the existence of a particular duty arising from a party's contractual duty of good faith is a question of law, while determining whether the particular duty was breached is a question of fact. This implication, too, is supported by case law from outside the Commonwealth. *See, e.g., Guardian Alarm Co. of Mich. v. May,* 24 Fed. Appx. 464 (6th Cir. 2001) ("The question of whether a party has adhered to the duty of good faith is properly decided by the jury. . . ."); *Questar Pipeline Co. v. Grynberg,* 201 F.3d 1277, 1290 (10th Cir. 2000) (holding that trial court properly determined what obligations were imposed by the contractual duty of good faith before allowing jury to determine whether duty was breached); *Youell v. Grimes,* 2001 U.S. Dist. LEXIS 1613, 2001 WL 121955, *2 (D. Kan. Feb. 8, 2001) ("Whether the underwriters breached their duty of good faith and thereby relieved the defendants of their duties under the contract is also a question of fact.").

[10] The economic loss doctrine initially applied solely to strict liability torts but has gradually been extended to negligence claims and, by some courts, to intentional torts as well. *See* Steven C. Tourek, Thomas H. Boyd & Charles J. Schoenwetter, *Bucking the "Trend": The Uniform Commercial Code, The Economic Loss Doctrine and Common Law Causes of Action for Fraud and Misrepresentation,* 84 Iowa L. Rev. 875, 885-891 (1999) (tracing the history of the economic loss doctrine nationwide).

[11] In reaching its conclusion, the *First Republic Bank* court relied on *All-Tech Telecom, Inc. v. Amway Corp.,* 174 F.3d 862 (7th Cir.1999); *KNK Medical- Dental Specialties, Ltd. v. Tamex Corp.,* 2000 U.S. Dist. LEXIS 14536, No. Civ. A. 99-

doctrine does not apply to Count VII - Fraudulent Misrepresentation.

[*25]

F. The Doctrine of Sovereign Immunity Protects SEPTA Against JHE's Claim for Fraudulent Misrepresentation and Request for Punitive Damages

Under 1 Pa. C.S. § 2310, "the Commonwealth, and its officials and employees acting within the scope of their duties, shall continue to enjoy sovereign immunity and official immunity and remain immune from suit except as the General Assembly shall specifically waive the immunity." The Pennsylvania Supreme Court has held that SEPTA is an agency of the Commonwealth and is therefore entitled to the general sovereign immunity protection afforded all Commonwealth agencies. *Feingold v. SEPTA,* 512 Pa. 567, 579, 517 A.2d 1270, 1276 (1986). *See also Warnecki v. SEPTA,* 689 A.2d 1023, 1025 (Pa. Commw. Ct. 1997) (holding that SEPTA is a "Commonwealth party" entitled to sovereign immunity protection).

Certain exceptions where the Commonwealth has waived sovereign immunity are set forth in 42 Pa. C.S. § 8522, which allows for tort claims based on the *negligent* acts related to the following:

. Vehicle liability;

. Medical-professional [*26] liability;

. Care, custody or control of personal property;

. Commonwealth real estate, highways and sidewalks;

. Potholes and other dangerous conditions;

. Care, custody or control of animals;

. Liquor store sales;

. National Guard activities; and

. Toxoids and vaccines.

42 Pa. C.S. § 8522(b). The Pennsylvania Supreme Court has instructed that courts "apply a rule of strict construction in interpreting these exceptions." *Jones v. SEPTA,* 565 Pa. 211, 220, 772 A.2d 435, 440 (2001) (citation omitted). *See also Finn v. City of Phila.,* 541 Pa. 596, 601, 664 A.2d 1342, 1344 (1995) ("Because the legislature's intent was to provide immunities, we have held that the exceptions to immunity must be strictly construed.").

As Pennsylvania law allows an exception to sovereign immunity for tort claims arising from negligent actions only, JHE's claim for fraudulent misrepresentation, an intentional tort, is legally insufficient. *See Frazier v. Southeastern Pa. Transp. Auth.,* 868 F. Supp. 757, 762 (E.D. Pa. 1994) (holding that plaintiff's fraud claim against Commonwealth agency was barred [*27] by sovereign immunity); *Faust v. Commonwealth, Dept. of Rev.,* 140 Pa. Commw. 389, 398, 592 A.2d 835, 839 (1991) ("Intentional tort claims and civil rights actions are not within the narrow exceptions set forth in 42 Pa.C.S. § 8522(b)"). Accordingly, it must be dismissed.

Similarly, Commonwealth agencies are entitled to protection against an award of punitive damages:

> Regarding retribution, it remains true that an award of punitive damages against a municipality "punishes" only the taxpayers, who took no part in the commission of the tort. These damages are assessed over and above the amount necessary to compensate the injured party. Thus, there is no question here of equitably distributing the losses resulting from official misconduct. Indeed, punitive damages imposed on a municipality are in effect a windfall to a fully compensated plaintiff, and are likely accompanied by an increase in taxes or reduction of public services for the citizens footing the bill. Neither reason nor justice suggests that such retribution should be visited upon the shoulders of blameless or unknowing taxpayers.

[*28] *Feingold,* 512 Pa. at 580-81, 517 A.2d at 1277 (quoting *Newport v. Fact Concerts, Inc.,* 453 U.S. 247, 267, 69 L. Ed. 2d 616, 101 S. Ct. 2748 (1981)) (internal citations omitted). Thus, JHE's demands for punitive damages must be stricken.

G. The Allegations in the Complaint Entitle JHE to an Award of Consequential Damages

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3409, 2000 WL 1470665 (E.D. Pa. Sept. 28, 2000); *Sunquest Info. Sys. v. Dean Witter Reynolds,* 40 F. Supp.2d 644 (W.D. Pa.1999); *Budgetel Inns, Inc. v. Micros Sys., Inc.,* 34 F. Supp.2d 720 (E.D. Wis.1999); *Stoughton Trailers, Inc. v. Henkel Corp.,* 965 F. Supp. 1227 (W.D. Wis.1997); *Palco Linings, Inc. v. Pavex, Inc.,* 755 F. Supp. 1269 (M.D. Pa.1990); *Comptech Int'l, Inc. v. Milam Commerce Park, Ltd.,* 753 So. 2d 1219 (Fla. 2000); R. Joseph Barton, *Drowning in a Sea of Contract: Application of the Economic Loss Rule to Fraud and Negligent Misrepresentation Claims,* 41 Wm. & Mary L. Rev. 1789 (2000); Tourek, Boyd & Schoenwetter, 84 Iowa L. Rev. at 885-891.

SEPTA next argues that JHE has not pled facts to support an award of consequential damages. Under Pennsylvania law, consequential damages may be awarded "(1) such as would normally and ordinarily result from the breach, or (2) that they were reasonably foreseeable and within the contemplation of the parties at the time they made the contract, and (3) that the damages can be proven." *Commonwealth, Dept. of Transp. v. Cumberland Constr. Co.,* 90 Pa. Commw. 273, 282, 494 A.2d 520, 525 (1985) (citing *Taylor v. Kaufhold,* 368 Pa. 538, 546, 84 A.2d 347, 351 (1951)). *Cf. Burly Constr. Corp. v. Commonwealth, Dept. of Justice,* 4 Pa. Commw. 46, 52, 284 A.2d 841, 844 (1971) (holding that contractor was "required to present evidence which afforded a sufficient basis for [*29] estimating the damages with reasonable certainty"). Here, JHE has indicated that it is seeking monetary damages amounting to $ 2,513,201.00 and has broken this sum down into discrete amounts for the value of additional work and overhead and lost bonding capacity and profits, among others. The allegations in the Complaint are sufficient to support the conclusion that these awards are normal, foreseeable and provable. As such, the challenge to the consequential damages JHE allegedly suffered is without merit.

III. Portions of the Complaint Are Insufficiently Specific

SEPTA also attacks the specificity of the Complaint in that it makes repeated references to unspecified "other" damages incurred and "other" representations of SEPTA. These allegations are improper and are stricken.

In presenting its argument, SEPTA relies on *Connor v. Allegheny General Hospital,* 501 Pa. 306, 461 A.2d 600 (1983). In *Connor,* the plaintiff's complaint alleged that, in addition to several specific acts of negligence, the defendant had "otherwise fail[ed] to use due care and caution under the circumstances." [*30] 501 Pa. at 310, 461 A.2d at 602. The Pennsylvania Supreme Court concluded that the plaintiff could amend her complaint to assert additional negligence allegations after the statute of limitations had run because the additional allegations merely would "amplify" the catch-all clause's claims. *Id.* In dicta, the court stated that any objections to the specificity of the catch-all clause should have been made at the pleadings stage and that the defendant waived its right to object by answering the complaint. 501 Pa. at 311 n.3, 461 A.2d at 602 n.3.

Pennsylvania trial courts have routinely relied on *Connor* to strike portions of complaints that are so general that they could permit a plaintiff to supplement allegations at a later point in time. *See, e.g., Philadelphia HGI Assocs., L.P. v. Cope Linder Assocs.,* 2001 Phila. Ct. Com. Pl. LEXIS 8, No. 2981, 2001 WL 1807792, at *2 (Pa. Com. Pl. Apr. 6, 2001) (plaintiff's "vague allegations about claims that may arise and damages that may occur in the future" were insufficiently specific); [*31] *Clarkson v. Geisinger Med. Clinic,* 46 Pa. D. & C.4th 431, 433 (2000) ("As a result of *Connor,* defendants are properly concerned about unidentified allegations of negligence arising late in the litigation process flowing out of a general allegation of negligence raised early in the process."); *Mitchell v. Remsky,* 39 Pa. D. & C.4th 122, 125 (1998) (General allegations of negligent conduct "represent[] an attempt by the plaintiff to preserve all unpleaded theories of liability against the moving defendants."); *Flurer v. Pocono Med. Ctr.,* 15 Pa. D. & C.4th 645, 671 (1992) ("Pennsylvania courts view this vague and all-inclusive language with disfavor."); *Hamilton v. American Cas. Co.,* 24 Phila. 354, 356 (1992) ("The language in the Plaintiff's Complaint which 'reserves the right to include additional claims for himself or his attorney' does not satisfy the pleading requirements under Rule 1019(a) and is unacceptable pleading in Pennsylvania."). [12]

[*32] JHE characterizes *Connor* as holding nothing more than "that the trial court erred in not permitting appellants to amend their complaint to amplify one of the allegations of the original complaint, and reversed the Superior Court's order affirming summary judgment in favor of appellee." Pl. Mem. 15 n.4. Pennsylvania trial courts, including this court, do not share this limited reading. As a result, those portions of the Complaint referring to unspecified "other" damages and conduct are insufficiently specific and must be stricken.

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[12] In at least one case, a trial court has held that a defendant's fears of future amendments that "amplify" general allegations are unfounded because language in *American States Insurance Co. v. State Auto Insurance Co.,* 721 A.2d 56 (Pa. Super. Ct. 1998), limits *Connor's* applicability. *See Fasula v. Hijazi,* 44 Pa. D. & C.4th 553, 565 (1999) ("According to the most recent appellate pronouncement, *Connor* simply states that a defendant may not obtain a compulsory nonsuit if the defendant does not request a more specific pleading . . . and does not obligate a defendant to preemptively object to general averments in order to safeguard against untimely pleadings."). However, no other court has read *American States Insurance Co.* in this way, and *Connor* continues to serve as a basis for striking broad catch-all allegations such as the one set forth in Paragraph 8(f) of the Complaint.

IV. Portions of the Complaint are Scandalous and Impertinent

SEPTA attacks certain statements in the Complaint as being scandalous and impertinent. Under Pennsylvania Rule of Civil Procedure 1028(a)(2), a party may object to a pleading's inclusion of "scandalous or impertinent matter." "Scandalous or impertinent matter" is defined as "allegations . . . immaterial and inappropriate to the proof of the cause of action." **Common Cause/Pa. v. Commonwealth,** 710 A.2d 108, 115 (Pa. Commw. Ct. 1998) (citing [*33] **Commonwealth, Dep't of Environmental Resources v. Peggs Run Coal Co.,** 55 Pa. Commw. 312, 423 A.2d 765 (1980)). Pennsylvania courts have been restrained in striking scandalous and impertinent pleadings, however:

> There is some authority for the proposition that, even if the pleading of damages was impertinent matter, that matter need not be stricken but may be treated as "mere surplusage" and ignored. . . . Furthermore, the right of a court to strike impertinent matter should be sparingly exercised and only when a party can affirmatively show prejudice.

Commonwealth, Department of Envtl. Resources v. Hartford Accident & Indemnity Co., 40 Pa. Commw. 133, 137-38, 396 A.2d 885, 888 (1979) (citations omitted).

SEPTA contends that JHE's allegations of recklessness, malicious intent and personal animosity are irrelevant to JHE's remaining causes of action, which assert claims for breach of contract, quantum meruit and estoppel. SEPTA is correct, as the emotions and intentions associated with SEPTA's alleged breach of the Contract or unjust enrichment have no bearing whatever on JHE's remaining claims. Moreover, it is not difficult [*34] to see how SEPTA is prejudiced by comments that portray it as being unscrupulous, and these extraneous comments must be stricken.

The Court disagrees with SEPTA as to the propriety of using the term "bad faith." To the extent that JHE uses the term "bad faith" to mean a breach of the covenant of good faith, it may be relevant to JHE's breach of contract claim and is therefore neither scandalous nor impertinent. Accordingly, the Objections to this term's use are overruled.

CONCLUSION

Because SEPTA's Objections asserting sovereign immunity can be addressed by looking at the face of the Complaint, JHE's Objections are overruled. Four of JHE's claims, as well as its demands for punitive damages, are legally insufficient and are dismissed. In addition, certain portions of the Complaint must be stricken because they are scandalous and impertinent or insufficiently specific. SEPTA's remaining Objections are overruled.

This court will enter a contemporaneous Order consistent with this Opinion.

BY THE COURT,

ALBERT W. SHEPPARD, JR., J.

ORDER

AND NOW, this 17th day of May 2002, upon consideration of the Preliminary Objections of defendant, [*35] Southeastern Pennsylvania Transportation Authority ("SEPTA"), to the Complaint of plaintiff, JHE, Incorporated, the plaintiff's response in opposition, and the plaintiff's Preliminary Objections to the defendant's Preliminary Objections and the defendant's response in opposition, the respective memoranda, all matters of record and in accord with the Opinion being filed contemporaneously with this Order, it is hereby **ORDERED** and DECREED as follows:

a. Plaintiff's Preliminary Objections to Preliminary Objections are **Overruled.**

b. Defendant's Preliminary Objections to Count II - Pennsylvania Public Works Bond Payment Act, Count V - Breach of Implied Duty of Good Faith and Fair Dealing, Count VI - Negligent Misrepresentation and Count VII - Fraudulent Misrepresentation are **Sustained,** and Counts II, V, VI and VII are **Dismissed.**

c. Defendant's Preliminary Objections to the plaintiff's demand for punitive damages is **Sustained,** and the demands for punitive damages are **Stricken.**

d. Defendant's Preliminary Objections asserting insufficient specificity are **Sustained, in part,** and Paragraphs 17, 43, 45, 46 and 47 of the [*36] Complaint are **Stricken.**

e. Defendant's Preliminary Objections asserting the inclusion of scandalous and impertinent material are **Sustained,** and Paragraphs 28, 34 and 52 of the Complaint are **Stricken.**

f. The remaining Preliminary Objections are **Overruled.**

g. Defendant shall file an answer to the Complaint within twenty-two (22) days of the date of this Order.

BY THE COURT,

ALBERT W. SHEPPARD, JR., J.

Shuker v. Smith & Nephew PLC

United States District Court for the Eastern District of Pennsylvania

March 31, 2015, Decided; March 31, 2015, Filed

CIVIL ACTION No. 13-6158

Reporter
2015 U.S. Dist. LEXIS 43141 *; 2015 WL 1475368

WALTER SHUKER, et al. v. SMITH & NEPHEW PLC, et al.

Subsequent History: Motion denied by *Shuker v. Smith & Nephew PLC, 2015 U.S. Dist. LEXIS 106816 (E.D. Pa., Aug. 13, 2015)*

Motion granted by, Dismissed by *Shuker v. Smith & Nephew PLC, 2016 U.S. Dist. LEXIS 134584 (E.D. Pa., Sept. 29, 2016)*

Core Terms

liner, metal, manufacturer, off-label, components, promotion, Plaintiffs', acetabular, premarket, amended complaint, preempted, hip, federal requirement, hip replacement, preemption, surgery, allegations, warnings, femoral, Cup, labeling, medical device, requirements, cleared, shell, leave to amend, devices, press release, resurfacing, purposes

Case Summary

Overview

HOLDINGS: [1]-A patient's state-law claims that a metal liner in a hip replacement system was unsafe and ineffective were subject to preemption under *21 U.S.C.S. § 360k* since the liner received pre-market approval as a medical device which was thus subject to federal requirements, even though the liner was used off-label as a component of the system which was federally approved as substantially equivalent to a preexisting device; [2]-The claims were preempted since the liner was identified as the source of the patient's injuries, the claims related to the safety of the liner when used with the system, and the state-law requirements were different from or in addition to federal requirements; [2]-A claim that the manufacturer failed to warn against using the liner with the hip replacement system was preempted as imposing a warning related to safety not required under federal law.

Outcome
Motion granted.

LexisNexis® Headnotes

Civil Procedure > ... > Summary Judgment > Entitlement as Matter of Law > Genuine Disputes

Civil Procedure > ... > Summary Judgment > Entitlement as Matter of Law > Materiality of Facts

Civil Procedure > Judgments > Summary Judgment > Entitlement as Matter of Law

HN1[] Under *Fed. R. Civ. P. 56*, summary judgment shall be granted if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. *Fed. R. Civ. P. 56(a)*. Material facts are those facts that might affect the outcome of the suit under the governing law. A factual dispute is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial.

Civil Procedure > ... > Defenses, Demurrers & Objections > Motions to Dismiss > Failure to State Claim

HN2[] To withstand a motion to dismiss for failure to state a claim pursuant to *Fed. R. Civ. P. 12(b)(6)*, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim is facially plausible when

the facts pleaded allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. In evaluating a Rule 12(b)(6) motion, a district court first must separate the legal and factual elements of the plaintiff's claims. The court must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions. The court must then determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a plausible claim for relief.

Civil Procedure > ... > Pleadings > Amendment of Pleadings > Leave of Court

HN3 Fed. R. Civ. P. 15 embodies a liberal approach to pleading, and leave to amend must generally be granted unless equitable considerations render it otherwise unjust. A district court has discretion to deny a request to amend, however, if it is apparent from the record that: (1) the moving party has demonstrated undue delay, bad faith or dilatory motives; (2) the amendment would be futile; or (3) the amendment would prejudice the other party. An amendment is futile if the amended complaint would not survive a motion to dismiss for failure to state a claim upon which relief could be granted.

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

Constitutional Law > Supremacy Clause > Federal Preemption

HN4 See 21 U.S.C.S. § 360k(a).

Constitutional Law > Supremacy Clause > Federal Preemption

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

HN5 The U.S. Supreme Court has established a two-step analysis for determining whether state tort claims with respect to a medical device are preempted under 21 U.S.C.S. § 360k(a). Since the Medical Device Amendments of 1976 (MDA) expressly preempts only state requirements different from, or in addition to, any requirement applicable to the device under federal law, a court must first determine whether the Federal Government has established requirements applicable to the device. If it has, the court must then determine whether the plaintiff's state-law claims are based upon state requirements with respect to the device that are different from, or in addition to the federal ones, and that relate to safety and effectiveness.

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

Constitutional Law > Supremacy Clause > Federal Preemption

HN6 If a medical device is subject to federal requirements, 21 U.S.C.S. § 360k(a) preempts those state requirements with respect to the device that are different from, or in addition to, the federal requirements and that relate to the safety and effectiveness of the device. Duties imposed pursuant to state tort law are requirements for purposes of the preemption provision; hence, state tort claims relating to the safety and effectiveness of a device are preempted to the extent that the state duties differ from or add to the federal requirements. Section 360k(a) does not, however, prevent a State from providing a damages remedy for claims premised on a violation of Food and Drug Administration regulations, as the state duties in such a case parallel, rather than add to, federal requirements. Section 360k(a) thus protects a manufacturer of a pre-market approved medical device from civil liability to the extent that it has complied with federal law, but it does not extend protection from liability where the claim is based on a violation of federal law.

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

HN7 See 21 U.S.C.S. § 360c(a)(2).

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

HN8 See 21 U.S.C.S. § 360e(d)(1)(A).

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

HN9[] By granting pre-market approval, the Food and Drug Administration requires the manufacturer of an approved medical device to place the device on the market in the form—and accompanied by the warnings and indications for use— approved by the agency, but does not prevent physicians from using the device in a different manner. 21 U.S.C.S. § 396.

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

HN10[] See 21 U.S.C.S. § 396.

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

Constitutional Law > Supremacy Clause > Federal Preemption

HN11[] A physician's decision to use a pre-market approved medical device off-label does not change the manufacturer's obligation to produce and market the device with almost no deviations from the specifications in its approval application; hence, the mere fact a device is used off-label does not render preemption under § 360k(a) inapplicable.

Constitutional Law > Supremacy Clause > Federal Preemption

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

Commercial Law (UCC) > ... > Contract Provisions > Warranties > Express Warranties

HN12[] The Medical Device Amendments of 1976 do not preempt claims for breach of express warranty as express warranties do not independently arise by operation of state law and claims for breach of such warranties thus do not involve state requirements.

Commercial Law (UCC) > ... > Contract Provisions > Warranties > Express Warranties

HN13[] Under Pennsylvania law, any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise. 13 Pa. Cons. Stat. § 2313. Because express warranties are specifically negotiated, to create an express warranty, the seller must expressly communicate the terms of the warranty to the buyer in such a manner that the buyer understands those terms and accepts them.

Healthcare Law > Medical Treatment > Medical Devices > Classification & Regulation

Constitutional Law > Supremacy Clause > Federal Preemption

HN14[] Because 21 U.S.C.S. § 360k(a) preempts only those state requirements with respect to a medical device that are different from, or in addition to, the federal requirements applicable to the device, the statute does not prevent a State from providing a damages remedy for claims premised on a violation of Food and Drug Administration regulations, as the state duties in such a case parallel, rather than add to, federal requirements. While a parallel claim must be based on the manufacturer's violation of federal law in order to avoid express preemption, the claim must not arise solely from the violation of Federal Food Drug and Cosmetic Act (FDCA) requirements, lest it be impliedly preempted as an attempt to privately enforce the FDCA. The claim must still be grounded in a violation of state-law duty. To plead a parallel claim successfully, a plaintiff's allegations must meet the plausibility standard. The plaintiff must plead that the manufacturer failed to comply with federal law and that this failure caused his injury.

Civil Procedure > ... > Pleadings > Heightened Pleading Requirements > Fraud Claims

HN15[] See Fed. R. Civ. P. 9(b).

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Judges: Juan R. Sánchez, J.

Opinion by: Juan R. Sánchez

Opinion

MEMORANDUM

Juan R. Sánchez, J.

Plaintiffs Walter and Vivian Shuker, husband and wife, bring this products liability action against Smith & Nephew, Inc. (S&N) and Smith & Nephew plc (PLC), seeking damages for injuries Walter Shuker sustained after undergoing hip replacement surgery with artificial hip components designed and manufactured by one or both Defendants. **[*2]** [1] Plaintiffs also seek damages for Vivian Shuker's loss of consortium. S&N has filed a motion for summary judgment,[2] asking this Court to grant judgment in its favor as to most of Plaintiffs' claims on the basis that the claims are preempted by the Federal Food Drug and Cosmetic Act (FDCA), as amended by the Medical Device Amendments of 1976 (MDA). Insofar as Plaintiffs assert potentially nonpreempted claims based on Defendants' alleged violations of common-law duties that parallel federal requirements applicable to the hip components in question, S&N asks the Court to dismiss the claims as inadequately pleaded. Plaintiffs oppose S&N's motion and also seek leave to file a Second Amended Complaint. For the reasons set forth below, the Court will grant Plaintiffs' motion for leave to amend and consider Defendants' arguments for summary judgment and/or dismissal as to Plaintiffs' Second Amended Complaint. Because the Court agrees with S&N that the claims set forth in the Second Amended Complaint are either preempted by the MDA or inadequately pleaded, S&N's motion for summary judgment and/or dismissal will be granted, and Plaintiffs' Second Amended Complaint will be dismissed in its entirety. The Court will, however, grant **[*3]** Plaintiffs leave to amend insofar as they seek to pursue parallel claims based on Defendants' off-label promotion of the hip components at issue.

BACKGROUND[3]

Defendants design and manufacture medical devices for use in hip replacement and hip resurfacing procedures. In a hip replacement, the surgeon covers the patient's hip socket (or acetabulum) with a cup and replaces the ball of the thighbone (the femoral head) with a metal ball attached to a long metal stem, which is inserted into the thighbone. *See* Pls.' Summ. J. Ex. A at 9050, 9052.[4] In a hip resurfacing procedure, the **[*4]** surgeon covers the hip socket with a cup and covers, rather than replaces, the femoral head with a cap. *See id*.

Defendants' hip replacement systems include the R3 Acetabular System (R3 System), which, according to Plaintiffs, consists of four main components: (1) an acetabular shell, (2) a cross-linked polyethylene (or poly) liner, (3) a femoral head, and (4) a femoral stem. *See* Second Am. Compl. ¶ 17. The R3 System is a Class II[5] medical device which the Food and Drug Administration (FDA) has authorized Defendants to

[1] PLC is the ultimate parent company of S&N. PLC denies that it conducts any business related to medical devices and has moved to dismiss this action for lack of personal jurisdiction. PLC's motion will be addressed by separate order.

[2] While styled as a motion for summary judgment, S&N's motion is actually a motion for summary judgment and/or dismissal.

[3] The following facts are drawn from the allegations of Plaintiffs' Second Amended Complaint and the evidence in the summary judgment record, all of which the Court construes in the light most favorable to Plaintiffs, drawing all reasonable inferences in their favor. *See* *Ashcroft v. Iqbal, 556 U.S. 662, 678-79, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009)*; *Hugh v. Butler Cnty. Family YMCA, 418 F.3d 265, 267 (3d Cir. 2005)*.

[4] Exhibits to Plaintiffs' opposition to S&N's motion for summary judgment are cited herein as "Pls.' Summ. J. Ex. __."

[5] Under the MDA, medical devices are classified in three categories, with different levels of federal oversight, based on the degree of risk they pose to the public. Class I is the lowest risk category; **[*5]** Class III is the highest.

market in the United States pursuant to what is known as the § 510(k) process.[6] Under the § 510(k) process, the FDA conducts a "limited form of review" of a new device and may permit the device to be marketed without further regulatory analysis if it determines, based on the manufacturer's submission, that the device is "substantially equivalent" to a preexisting device. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 478, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996).[7]

Defendants also manufacture the Birmingham Hip Resurfacing (BHR) System, a Class III hip resurfacing system consisting of two main components: (1) a socket in the shape of shallow cup (the acetabular component), which replaces the damaged surface of the hip socket, and (2) a cap in the form of a ball head (the femoral resurfacing component), which covers the femoral head. *See* Pls.' Summ. J. Ex. A at 9050-51; Rouss Decl. ¶ 5. The cap has a small stem that is inserted into the top of the thighbone. *See* Pls.' Summ. J. Ex. A at 9051. Both the acetabular component and **[*7]** the femoral resurfacing component of the BHR system are made of metal; hence, the System is referred to as having a metal-on-metal coupling or articulation. In contrast to the R3 System, which entered the market via the § 510(k) process, the BHR System underwent the substantially more rigorous premarket approval (PMA) process, whereby approval is granted only if FDA finds, after reviewing the manufacturer's voluminous application materials, that "there is a 'reasonable assurance' of the device's 'safety and effectiveness.'"[8] *See* Riegel v. Medtronic, Inc., 552 U.S. 312 317-18, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008) (quoting 21 U.S.C. § 360e(d)). The FDA granted Defendants'[9] application for premarket approval of the BHR system in May 2006. Rouss Decl. Ex. A.

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[6] The FDA's authorization with respect to the R3 System is reflected in a series of notifications pertaining to different components of the System. *See* Pls.' Summ. J. Ex. A at 13354-55 (September 12, 2006, notification of § 510(k) authorization for "Smith & Nephew Modular Femoral (Hemi) Heads"); *id*. at 13433-44 (October 17, 2005, notification of § 510(k) authorization for "ANTHOLOGY Hip Stem"); Rouss Decl. Ex. F (June 6, 2007, notification of § 510(k) authorization for "Smith and Nephew REFLECTION 3"). There is no single 510(k) notification covering all four components Plaintiffs identify as part of the R3 System, and S&N's "510(k) Summary" for the System describes it as consisting only of "Acetabular shells and liners." Rouss Decl. Ex. G. Nevertheless, the Court assumes, for purposes of this Memorandum, that the R3 System consists of all of the components identified by Plaintiffs. *See* Pls.' Summ. J. Ex. A at 10002 (PMA supplement excerpt for the Birmingham Hip Resurfacing System describing a Smith and Nephew "total hip replacement system . . . consisting of the R3 Acetabular Shell, poly liner, femoral stem and femoral head" as a Class II device); *id*. at 12535 (March 2012 FDA email suggesting the agency's § 510(k) review **[*6]** of S&N's "R3 XLPE Acetabular Liners" includes review of the compatible femoral heads and stems that are part of the same hip system).

[7] Class I and Class II devices are subject to the § 510(k) process. *See* Lohr, 518 U.S. at 478. Class III devices are generally subject to the separate premarket approval process, described in greater detail below, but a Class III device may enter the market via the § 510(k) process if the FDA finds it is substantially equivalent to a grandfathered device, i.e., a device already on the market before the MDA's effective date and permitted to remain on the market until the FDA promulgates a regulation requiring premarket approval. *See* Riegel v. Medtronic, Inc., 552 U.S. 312, 317, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008).

[8] To obtain premarket approval, a manufacturer must submit to the FDA "what is typically a multivolume application," including, inter alia,

> full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, **[*8]** packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

Riegel, 552 U.S. at 317-18 (citation and internal quotation marks omitted). In reviewing a PMA application—a process on which the FDA spends an average of 1,200 hours per application—the agency may request additional data from the manufacturer and may seek input from outside experts. *See id*. As noted, the FDA grants premarket approval "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness,'" *id*. (quoting 21 U.S.C. § 360e(d)), after weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," *id*. (quoting 21 U.S.C. § 360c(a)(2)(C)). Once premarket approval is granted, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." Id. at 319.

[9] The Court notes that the FDA directed its notification that the BHR System had received premarket approval to "Smith & Nephew Orthopaedics" at the same Memphis, Tennessee, address where S&N is located. *See* Rouss Decl. Ex. A.

The following year, in April **[*9]** 2007, Defendants filed a PMA application supplement, seeking approval for a line extension to the BHR System consisting of a modular version of the BHR cup. Rouss Decl. ¶ 6 & Exs. B & C. The modular BHR cups, referred to as R3 Metal on Metal Cups, consist of an R3 acetabular shell made of titanium alloy and an R3 metal liner made of cobalt-chromium alloy. Rouss Decl. Ex. C. The PMA supplement represented that the metal-on-metal articulation of the BHR System with the modular cups would be unchanged from that of the System with the one-piece cups the FDA had previously approved. *See id*.; Pls.' Ex. A at 9999. On November 13, 2008, the FDA approved the PMA supplement and granted Defendants permission to distribute the BHR System with the modular cups. Rouss Decl. Ex. B. The FDA also approved labeling[10] associated with the line extension, including a surgical technique addendum covering use of the modular R3 Metal on Metal Cups within the BHR System. Rouss Decl. ¶ 8 & Ex. D. The surgical technique addendum specifically notes that "in the US, the R3 metal liner is intended for use as part of the BHR system only," cautioning that if the resurfacing procedure is abandoned "in favor of a total **[*10]** hip replacement, the R3 acetabular shell must be used with a mating R3 poly liner." Rouss Decl. Ex. D at 12157, 12159. The addendum also cautions that if, post-operatively, "the BHR resurfacing head must be revised to a total hip arthroplasty [i.e., replacement], . . . the R3 acetabular shell can remain in place if well-fixed," but "the R3 metal liner must be replaced with an R3 poly liner, which can be used with any compatible legally marketed Smith & Nephew femoral stem and mating ceramic or metal femoral head component." *Id*. at 12159.

In February 2009, four months after the R3 Metal on Metal Cup received premarket approval as part of the BHR System, S&N issued a press release announcing "the introduction of a metal liner option for its R3 Acetabular System, an advanced multi-bearing cup system used in hip replacement and resurfacing procedures." S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. A;[11] *see also* Second Am. Compl. ¶ 91. The press release noted the FDA had recently approved the metal **[*11]** liner for use with the BHR System, but said nothing about the regulatory status of the liner for use in total hip replacements.[12] S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. A. The press release touted the R3 System's unique capacity to "accommodate[] the major advanced bearing options, including metal-on-metal, ceramic-on-ceramic, cobalt chrome on cross-linked polyethylene (XLPE), and the company's exclusive OXINIUM™ Oxidized Zirconium on XLPE," and described the R3 System's multi-bearing cup as providing "intraoperative flexibility for surgeons" and "solutions designed to reduce wear and the subsequent need for revision surgery." *Id*.

On April 29, 2009, Walter Shuker underwent right total hip replacement surgery in which his surgeon, Kevin Terefenko, M.D., implanted the following components manufactured by Defendants: (1) a modular femoral head made of cobalt-chrome, (2) a modular head sleeve made of cobalt-chrome, (3) a femoral stem component, (4) an R3 no-hole hemispherical acetabular shell, and (5) an R3 acetabular liner made of cobalt-chrome, i.e., an R3 metal liner. Pls.' Summ. J. Ex. C at 2; Pls.' Summ. J. Ex. E. The first four components used in Mr. Shuker's hip replacement surgery were cleared by the FDA pursuant to the § 510(k) process.[13] The R3 metal liner

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[10] For purposes of the FDCA, the term labeling means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *21 U.S.C. § 321(m)*.

[11] Although the Second Amended Complaint quotes from the press release, the press release is not included as an exhibit to the Complaint, nor is it part of the summary judgment record. S&N has produced a copy of the press release as an exhibit to its opposition to Plaintiffs' motion for leave to amend. Because Plaintiffs' claims are based on the press release, the Court may properly consider it, even in evaluating the sufficiency of Plaintiffs' claims. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 322, 127 S. Ct. 2499, 168 L. Ed. 2d 179 (2007)* (holding a court may consider "documents incorporated into the court by reference" in evaluating **[*12]** a motion to dismiss).

[12] Defendants did not seek FDA approval to use the R3 optional metal liner with the R3 System. *See* Second Am. Compl. ¶ 96. Outside the United States, however, the liner received regulatory approval for use in a total hip replacement. *See* S&N's Opp'n to Pls.' Mot. for Leave to *Amend 9* & Ex. C.

[13] *Compare* Pls.' Summ. J. Ex. E (chart-stik labels showing catalog numbers for components used in Mr. Shuker's surgery), *with* Pls.' Summ. J. Ex. A at 13354-55, 13361, 13433-34, 13466 (§ 510(k) notifications and catalog numbers for femoral head, head sleeve, and femoral stem component), *id*. at 12188, 13178 (catalog numbers for R3 no-hole acetabular shell), *and* Rouss Decl. Ex. F (§ 510(k) notification for acetabular shell). The R3 acetabular shell used in Mr. Shuker's surgery also appears to have received premarket approval as part of the BHR System. *See* Rouss Decl. ¶ 9;

component, however, did not receive FDA § 510(k) clearance as part of the R3 System. Rather, the metal liner was part of the R3 Metal on Metal Cup that received premarket approval as part of the BHR System. *See* Rouss Decl. ¶ 9; *compare* Pls.' Summ. J. Ex. E (chart-stik labels), **[*13]** *with* Rouss Decl. Ex. D at 12161 (catalog numbers for R3 metal liners). The FDA did not approve the R3 metal liner for use with the R3 System in a total hip replacement procedure. Dr. Terefenko's use of the metal liner component in Mr. Shuker's surgery was thus an "off-label" use, i.e., a use for a purpose other than "that for which it has been approved by the FDA." *See* *Buckman Co. v. Pls.' Legal Comm., 531 U.S. 341, 350, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001)*.

Approximately 21 months after his surgery, Mr. Shuker began developing **[*14]** increasing pain and discomfort in his buttocks, groin, and thigh, limiting his daily activities. Second Am. Compl. ¶ 110. On May 23, 2011, he underwent an aspiration procedure, performed by Dr. Terefenko, during which a milky brown tinged fluid and metallic debris were removed from his body. *Id*. ¶ 111. Dr. Terefenko determined Mr. Shuker's pain was caused by metal sensitivity due to the degeneration of the metal-on-metal articulation of his artificial hip and decided that replacement of the metal-on-metal articulation was necessary to relieve the pain. *Id*. On July 6, 2011, Mr. Shuker underwent a further hip surgery during which Dr. Terefenko replaced the existing metal-on-metal articulation with an Oxinium head and a polyethylene liner. *Id*. ¶ 112. After the surgery, Mr. Shuker again developed extreme pain in his right hip. *Id*. ¶ 113. Dr. Terefenko performed a second aspiration procedure on November 12, 2012, and determined that Mr. Shuker had developed an infection at the surgery site. *Id*. In December 2012 and January 2013, Mr. Shuker underwent further surgeries to remove and replace the R3 System. *Id*. ¶¶ 114-15.

In June 2012, almost a year after Mr. Shuker's surgery to replace the **[*15]** metal-on-metal articulation of the components originally implanted, Defendants announced they had "chosen to withdraw the optional metal liner component within the R3 Acetabular System." *Id*. ¶ 99; *see also* Pls.' Summ. J. Ex. A at 13963. Defendants explained the withdrawal was a "precautionary measure" based on data from sources including "Australian and [United Kingdom] patient registries," which indicated the metal liner component within the R3 System was not performing as well as the company would like. Second Am. Compl. ¶ 100. That same month, the Medicines and Healthcare Products Regulatory Agency (MHRA), the analogue of the FDA in the United Kingdom, advised surgeons to stop using the R3 metal liner because of the higher revision rates associated with it than with nonmetal liners.[14] *Id*. ¶ 102. The MHRA also advised surgeons to annually monitor those patients who had been fitted with the metal liners to ensure that "any complications such as pain or swelling [would be] picked up and treated early." *Id*. At the time of the withdrawal, a majority of the R3 metal liners in use globally had been used in hip replacement, rather than resurfacing, procedures. *See* Pls.' Summ. J. Ex. A at **[*16]** 13693.

In September 2013, Plaintiffs commenced the above-captioned action by filing a Complaint in the Court of Common Pleas of Philadelphia County. S&N removed the case to federal court the following month and, after answering the Complaint, filed a motion for judgment on the pleadings. Following a Rule 16 conference at which Plaintiffs indicated their desire to amend their Complaint, the Court granted Plaintiffs leave to amend and denied S&N's motion for judgment on the pleadings without prejudice.

In December 2013, Plaintiffs filed their First Amended Complaint, asserting claims for negligence/negligence per se, negligence based on violations of various FDA regulations, strict products liability, breach of express warranty, breach of implied warranties of merchantability, fraud, and loss of consortium. S&N thereafter filed a motion to dismiss, arguing Plaintiffs' claims were expressly preempted by the preemption provision **[*17]** of the MDA, *21 U.S.C. § 360k*, and were inadequately pleaded insofar as Plaintiffs attempted to assert a nonpreempted negligence claim premised on violations of FDA regulations. S&N's preemption argument was based on the assertion that the R3 metal liner used in Mr. Shuker's hip replacement surgery received premarket approval, an assertion that Plaintiffs disputed in their First Amended Complaint. Although S&N submitted certain FDA documents in support of its

compare Pls.' Summ. J. Ex. E (chart-stik labels), *with* Rouss Decl. Ex. D at 12161 (catalog numbers for R3 no-hole acetabular shell component of the R3 modular resurfacing acetabular cup, i.e., the R3 Metal on Metal Cup).

[14] The MHRA reported the revision rate for the R3 metal liner was 6.4% at four years, which not only was higher than the revision rate for nonmetal liners, but also exceeded the "4% guidance figure at four years from National Institute of Health and Clinical Excellence." *Id*. ¶ 102.

position, this Court found the documents, standing alone, were insufficient to establish the regulatory status of the metal liner used in Mr. Shuker's surgery, and the Court therefore denied the motion to dismiss. Recognizing that the preemption issue was potentially dispositive of most (if not all) of Plaintiffs' claims, however, the Court amended the scheduling order to permit the parties to take discovery on the preemption issue, following which S&N could to renew its preemption argument in a motion for summary judgment. The Court deferred ruling on the sufficiency of Plaintiffs' parallel claim pending the re-briefing of the preemption issue.

S&N has now renewed its preemption argument on summary judgment, asserting Plaintiffs' claims are preempted **[*18]** and their attempt to plead a nonpreempted parallel claim remains unavailing. After S&N filed its summary judgment motion, Plaintiffs filed a motion for leave to file a Second Amended Complaint to clarify the regulatory history and status of the artificial hip implanted in Mr. Shuker, to refine causes of action based on Defendants' active promotion of off-label uses of their products, and to clarify their parallel claims.

APPLICABLE LEGAL STANDARDS

S&N seeks summary judgment as to most of Plaintiffs' claims on the ground that the claims are preempted. ***HN1***[] Under *Federal Rule of Civil Procedure 56*, summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Fed. R. Civ. P. 56(a)*. Material facts are those facts "that might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986)*. A factual dispute is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id*. "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986)* (citation omitted).

S&N also seeks dismissal of any nonpreempted claims based on Defendants' **[*19]** alleged violation of common-law duties that parallel federal requirements on the ground that such claims are inadequately pleaded and thus fail to state a claim on which relief can be granted. ***HN2***[] To withstand a motion to dismiss pursuant to *Federal Rule of Civil Procedure 12(b)(6)*, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009)* (quoting *Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007))*. A claim is facially plausible when the facts pleaded "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. In evaluating a *Rule 12(b)(6)* motion, a district court first must separate the legal and factual elements of the plaintiff's claims. *See Fowler v. UPMC Shadyside, 578 F.3d 203, 210 (3d Cir. 2009)*. The court "must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." *Id. at 210-11*. The court must then "determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id. at 211* (quoting *Iqbal, 556 U.S. at 679*).

In addition to opposing S&N's motions, Plaintiffs seek leave to file a Second Amended Complaint pursuant to *Federal Rule of Civil Procedure 15(a)*. ***HN3***[] *Rule 15* "embodies a liberal approach to pleading," and leave to amend "must generally be granted unless equitable considerations render **[*20]** it otherwise unjust." *Arthur v. Maersk, Inc., 434 F.3d 196, 202, 204 (3d Cir. 2006)*; *see also Fed. R. Civ. P. 15(a)(2)* (directing that courts "should freely give leave [to amend] when justice so requires"). A district court has discretion to deny a request to amend, however, "if it is apparent from the record that (1) the moving party has demonstrated undue delay, bad faith or dilatory motives, (2) the amendment would be futile, or (3) the amendment would prejudice the other party." *Hill v. City of Scranton, 411 F.3d 118, 134 (3d Cir. 2005)*. "An amendment is futile if the amended complaint would not survive a motion to dismiss for failure to state a claim upon which relief could be granted." *Alvin v. Suzuki, 227 F.3d 107, 121 (3d Cir. 2000)*.

DISCUSSION

Plaintiffs' First Amended Complaint is based on the faulty premise that the R3 metal liner was a component of the § 510(k)-cleared R3 System. Discovery has confirmed that the only regulatory approval the R3 metal liner received in the United States is premarket approval as part of the BHR System. In their proposed Second Amended Complaint, Plaintiffs seek to correct their allegations regarding the regulatory status of the metal liner and the other components used in Mr. Shuker's hip replacement surgery, and, in light of these changes, to

refine their allegations in support of a nonpreempted parallel claim based on Defendants' alleged **[*21]** violations of federal law. S&N opposes Plaintiffs' motion for leave to amend solely on the basis that permitting the amendment would be futile because the Second Amended Complaint still fails to plead a viable claim. Because the regulatory status of the components implanted in Mr. Shuker is essential to the Court's determination of what claims Plaintiffs can and cannot pursue, and because S&N does not suggest it would be prejudiced by the amendment, the Court will grant Plaintiffs' motion for leave to amend and will consider S&N's arguments for summary judgment and dismissal as to Plaintiffs' Second Amended Complaint.

S&N argues most of Plaintiffs' claims are preempted by the MDA's express preemption provision, which, subject to an exception not applicable here, provides:

> ***HN4***[] [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). ***HN5***[] The Supreme **[*22]** Court has established a two-step analysis for determining whether state tort claims with respect to a medical device are preempted under *§ 360k(a)*. "Since the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law," a court must first determine "whether the Federal Government has established requirements applicable to [the device]." *Riegel, 552 U.S. at 321* (quoting *§ 360k(a)(1)*). If it has, the court must then determine whether the plaintiff's state-law claims "are based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id. at 321-22* (quoting *21 U.S.C. § 360k(a)*).

As to the first step in the preemption analysis, the Supreme Court has held "[p]remarket approval . . . imposes 'requirements' under the MDA." *Id. at 322*. Section 510(k) clearance does not. *Id*. In explaining the distinction between the two forms of approval for preemption purposes, the Court noted that whereas *§ 510(k)* is "focused on *equivalence*, not safety," *id. at 323* (quoting *Lohr, 518 U.S. at 493*), premarket approval "*is* federal safety review" *id*. Moreover, while devices cleared under *§ 510(k)* are subject only to general federal regulations "applicable across the board **[*23]** to almost all medical devices," premarket approval is device-specific. *See id. at 322-23*. Indeed, once premarket approval is granted, the FDA requires the device "to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id. at 323*; *see also Horn v. Thoratec Corp., 376 F.3d 163, 170-72 (3d Cir. 2004)* (holding premarket approval imposes federal requirements on a device and noting the FDA's position that a premarket approval order from the agency "specifically approves as a matter of law those features set forth in the application and binds the manufacturer to produce and market the product in compliance with the specifications as approved by FDA" (emphasis omitted)). Medical devices that enter the market via the PMA process are thus subject to federal requirements for purposes of *§ 360k(a)*.

HN6[] If a device is subject to federal requirements, *§ 360k(a)* preempts those state requirements "with respect to [the] device" that are "different from, or in addition to," the federal requirements and that "relate[] to the safety and effectiveness of the device." Duties imposed pursuant to state tort law are "requirements" for purposes of **[*24]** the preemption provision, *Riegel, 552 U.S. at 324*; hence, state tort claims relating to the safety and effectiveness of a device are preempted to the extent that the state duties differ from or add to the federal requirements. *Section 360k(a)* does not, however, "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations," as "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id. at 330*. *Section 360k(a)* thus protects a manufacturer of a PMA-approved medical device from civil liability "to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law." *Bausch v. Stryker Corp., 630 F.3d 546, 552 (7th Cir. 2010)*.

After discovery, it is now undisputed that the R3 metal liner used in Mr. Shuker's surgery received premarket approval as part of the BHR System, while the rest of the components were cleared pursuant to the § 510(k)

process.[15] It is also undisputed that the FDA never approved the particular combination of components implanted in Mr. Shuker for use together as a single device. The parties disagree as to whether and how the MDA's preemption provision applies in these unusual circumstances in which a physician uses a component from a PMA-approved **[*25]** device off-label with components from a § 510(k)-cleared device.

S&N argues because the liner received premarket approval as part of the BHR System, there are federal requirements applicable to the liner, and Plaintiffs' tort claims, all of which relate to the safety and effectiveness of the liner in some way, are preempted, with the exception of Plaintiffs' claim based on violations of FDA regulations and FDCA provisions.[16] S&N maintains the fact that Dr. Terefenko used the liner off-label with components of a device that was otherwise § 510(k)-cleared does not deprive the liner of the protections of § 360k(a).

Plaintiffs dispute that the R3 metal liner is itself a device subject to federal requirements when used outside of the BHR System. Noting that the FDA approves hip systems, not individual components, Plaintiffs argue the hip system implanted in Mr. Shuker, which consisted predominantly of components from the § 510(k)-cleared R3 System, should be regarded for preemption purposes **[*26]** either as a § 510(k) device or as a new Class III device that has not received either § 510(k) clearance or premarket approval. Either way, Plaintiffs contend that because the device at issue—i.e., the entire hip system Mr. Shuker received—never underwent the PMA process, § 360k(a) is inapplicable. Alternatively, Plaintiffs contend Defendants forfeited the benefits of preemption by promoting the R3 metal liner for use off-label with the R3 System.

Although there is scant case law addressing how the MDA's preemption provision applies with respect to a component of device that has received premarket approval when used independently of the remainder of the device, two federal district courts in New York have considered this question with respect to the same Smith & Nephew components at issue here. *See* Bertini v. Smith & Nephew, Inc., 8 F. Supp. 3d 246 (E.D.N.Y. 2014); Simon v. Smith & Nephew, Inc., 990 F. Supp. 2d 395 (S.D.N.Y. 2013), *reconsideration denied*, 18 F. Supp. 3d 423 (S.D.N.Y. Mar. 26, 2014). Both cases involved plaintiffs who, like Mr. Shuker, had hip replacement surgery in which their surgeons implanted them with the R3 System and the optional R3 metal liner. Both plaintiffs eventually experienced problems with their artificial hips and, after undergoing revision surgery, sued S&N, asserting products liability-related claims, which S&N moved to dismiss as both preempted **[*27]** and inadequately pleaded. With regard to preemption, in both cases, the courts concluded that because the R3 metal liner had received premarket approval as part of the BHR System, claims with respect to the liner were preempted. *See* Simon, 18 F. Supp. 3d at 428; Bertini, 8 F. Supp. 3d at 254. The courts rejected the argument that use of the liner outside of the BHR System affected the preemption analysis, noting the question under § 360k(a) "is not whether there are federal requirements applicable to a particular *use* of a device," but "whether there are federal requirements applicable to the *device*." Simon, 18 F. Supp. 3d at 428 (quoting Riley v. Cordis Corp., 625 F. Supp. 2d 769, 779 (D. Minn. 2009) (internal quotation marks omitted)); *see also* Bertini, 8 F. Supp. 3d at 255. While both courts suggested claims relating solely to the § 510(k)-cleared components of the R3 System would not be preempted, they concluded the plaintiffs had not pleaded any nonpreempted claims, as the product defects the plaintiffs identified pertained either to the R3 metal liner itself or to the liner's interface with other components. *See* Simon, 18 F. Supp. 3d at 428-29 (holding whether the plaintiff's injuries were "understood to have resulted from [the R3 metal] liner alone . . . or from use of that liner in combination with other components of the R3 Acetabular System . . . , the metal liner [wa]s at the heart of each and every **[*28]** one of [plaintiff's] claims" and the claims were therefore preempted); Bertini, 8 F. Supp. 3d at 255-58.

The Court agrees with the Simon and Bertini courts that insofar as Plaintiffs' claims challenge the safety and effectiveness of the R3 metal liner, the claims are preempted under § 360k(a). As both of those courts recognized, preemption under § 360k(a) turns on whether there are federal requirements "applicable . . . to the device" and, if so, whether the plaintiff's state tort claims would impose requirements relating to the safety or effectiveness of the device that are "different from, or in addition to," the federal requirements. 21 U.S.C. § 360k(a); *see also* Riegel, 552 U.S. at 321-22. Upon the FDA's approval of Defendants' PMA application for the multi-component BHR System and PMA supplement for

[15] As noted, the R3 acetabular shell appears to have been both PMA-approved and § 510(k)-cleared.

[16] Although S&N does not contend this parallel claim is preempted, it argues the claim should nevertheless be dismissed because it is inadequately pleaded.

the R3 Metal on Metal Cup, Defendants were required to produce and market the device, including all of its constituent components, in accordance with the specifications approved by the FDA. *See* Riegel, 552 U.S. at 323; Horn, 376 F.3d at 170-72; *see also* 21 U.S.C. § 321(h) (defining the term "device" to include "any component, part, or accessory" thereof). Thus, under *Riegel*, the FDA's approval of the PMA supplement for the R3 Metal on Metal Cup imposed federal requirements on the Cup—and on the R3 metal liner, a component of the Cup—for purposes **[*29]** of § 360k(a). *See, e.g.,* Hawkins v. Medtronic, Inc., No. 13-499, 2014 U.S. Dist. LEXIS 11779, 2014 WL 346622, at *5 (E.D. Cal. Jan. 30, 2014) ("The requirements set forth in the premarket approval for the entire device are just as applicable to the components that together form the FDA-approved device as the device itself."); Eidson v. Medtronic, Inc. (Eidson I), 981 F. Supp. 2d 868, 881 n.3 (N.D. Cal. 2013) (holding premarket approval of a three-component medical device established federal requirements for two components of the device when used without the third).

Plaintiffs argue the fact that the R3 metal liner received premarket approval for use with the BHR System is irrelevant because Dr. Terefenko used it as part of a different hip system, which was not PMA-approved. Citing a statement from an FDA employee that the agency "review[s] hip systems and not individual components," Pls.' Summ. J. Ex. A at 12535, Plaintiffs argue the Court must look at the hip system implanted in Mr. Shuker as a whole in applying the preemption analysis. While this approach makes sense in cases in which the FDA has actually reviewed the particular system at issue, that is not the case here, as the R3 System the FDA cleared via the § 510(k) process did not include the R3 metal liner. There is thus no basis to characterize the hip system implanted in Mr. Shuker as the § 510(k)-cleared R3 System.

The fact that the FDA never reviewed **[*30]** the particular hip system Mr. Shuker received via either the § 510(k) or the PMA process distinguishes this case from the cases Plaintiffs cite in which courts have held the preemption analysis cannot be applied differently to individual components of a multi-component medical device, but must be applied to the device as a whole. In all of those cases, the device as a whole received premarket approval, generally as a result of the FDA's approval of a PMA supplement permitting the manufacturer to incorporate a component that previously received § 510(k) clearance into a PMA-approved device. In that situation, courts have uniformly rejected the argument that the § 510(k)-cleared component was not subject to express preemption, holding the approval of a PMA supplement incorporating the § 510(k)-cleared component extended premarket approval to the entire device. *See* Gross v. Stryker Corp., 858 F. Supp. 2d 466, 485-88 (W.D. Pa. 2012); Duggan v. Medtronic, Inc., 840 F. Supp. 2d 466, 471-72 (D. Mass. 2012); Lewkut v. Stryker Corp., 724 F. Supp. 2d 648, 656-57 (S.D. Tex. 2010); *see also* Bass v. Stryker Corp., 669 F.3d 501, 508 & n.1 (5th Cir. 2012) (upholding a district court's finding that an acetabular shell that the plaintiff maintained was not subject to premarket approval testing was part of the PMA-approved hip replacement system at issue). None of these cases involved a device created by a physician's off-label use of a PMA-approved component with components of a § 510(k)-cleared system. **[*31]** If anything, the cases reinforce the conclusion that approval of the PMA supplement for the R3 Metal on Metal Cup imposed federal requirements on the R3 metal liner as a component of the Cup.[17]

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[17] In *Huskey v. Ethicon, Inc.*, a case cited by Plaintiffs as supplemental authority, the court applied the converse of the principle applied in the cases cited above, holding that "[j]ust as 'a device receiving premarket approval cannot be separated into its component parts to avoid application of express preemption,' a device receiving 510(k) approval cannot be separated into its component parts to create express preemption." 29 F. Supp. 3d 736, 748 (S.D. W. Va. 2014) (citations omitted). Plaintiffs argue the principle recognized in *Huskey* applies equally here. But this argument overlooks the critical fact that the particular assemblage of components Mr. Shuker received was never cleared as a single device via the § 510(k) process. While it may "make[] no sense" to apply a different preemption analysis to different components of a device the FDA has authorized the manufacturer to market as a single medical device, *see id*. (citation omitted), this case does not involve such a device, and *Huskey* is therefore inapposite.

It also bears mention that the preemption **[*32]** argument the court rejected in *Huskey* was significantly broader than the argument S&N advances in this case. *Huskey* concerned a § 510(k)-cleared medical device called the Gynecare TVT Obturator (or TVT-O), which included a mesh tape, or sling, made of Prolene polypropylene filaments, the same material used in the Prolene suture, a separate, PMA-approved medical device. The manufacturer argued because the suture, which consisted of single Prolene filament, received premarket approval, the plaintiffs' claims that the Prolene filaments in the mesh tended to degrade were preempted. Although the court rejected this argument on the basis that the TVT-O as a whole had been cleared via the § 510(k) process and thus could not

As Plaintiffs note, the FDA's approval of the R3 metal liner was predicated on Defendants' representations regarding its intended use as part of the BHR System. *See* 21 U.S.C. § 360c(a)(2) (providing that, for purposes of premarket approval, ***HN7***[⬆] "the safety and effectiveness of a device are to be determined . . . with respect to the persons for whose use the device is represented or intended [and] with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device"); *id*. § 360e(d)(1)(A) (providing that in determining whether to approve or deny a PMA application, ***HN8***[⬆] "the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading"). But while the FDA **[*34]** considers the intended use of a device in determining whether to grant premarket approval, the requirements such approval imposes on a device are not use-specific, as the FDA does not regulate the use of medical devices—or their components—by physicians, who remain free to use such devices in an off-label manner. *See, e.g., Ramirez v. Medtronic, Inc., 961 F. Supp. 2d 977, 988 (D. Ariz. 2013)*. In other words, ***HN9***[⬆] by granting premarket approval, the FDA requires the manufacturer of an approved device to place the device on the market in the form—and accompanied by the warnings and indications for use— approved by the agency, but does not prevent physicians from using the device in a different manner. *See* 21 U.S.C. § 396 (providing ***HN10***[⬆] "[n]othing in [the FDCA] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship"); *Buckman, 531 U.S. at 350* (recognizing "'off-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine"). ***HN11***[⬆] A physician's decision to use a PMA-approved device off-label does not **[*35]** change the manufacturer's obligation to produce and market the device "with almost no deviations from the specifications in its approval application," *Riegel, 552 U.S. at 323*; hence, the mere fact a device is used off-label does not render § 360k(a) inapplicable. *See id. at 320, 322-23* (holding the premarket approval of a balloon catheter imposed federal requirements on the catheter under the MDA notwithstanding that the plaintiff's physician had used the device in a manner contraindicated by the product labeling); *Perez v. Nidek Co., 711 F.3d 1109, 1118 (9th Cir. 2013)* (holding a laser system approved via the PMA process for treating nearsightedness was "subject to device-specific requirements under the PMAs," even when used in surgery to treat farsightedness).[18] As one district court has observed, if the law were otherwise,

> a manufacturer of a medical device could scrupulously adhere to the FDA's every command—and meet every requirement imposed on the design, manufacture, labeling, and marketing of the device—and nevertheless be sued under the tort law of any of the fifty states because a health-care provider, without the manufacturer's consent or even knowledge, decided to put the device to an off-label use.

Riley, 625 F. Supp. 2d at 778.[19]

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be separated into its component parts for purposes of conducting a preemption analysis, the suture was not so much a component of the TVT-O as a device made of the same material. The court thus rejected the notion that the FDA's grant of premarket approval for a device made of a particular material constituted approval of that material for all purposes, explaining, by way of analogy: "If a specific type of metal were approved for use in a bone screw via the premarket approval process, **[*33]** it would not follow that that same type of metal was safe in all medical devices, no matter what their function in the human body." *Id. at 747* (citation omitted).

The Court also notes that insofar as *Huskey* rejected the analysis in *Simon* and *Bertini*, it did so based at least in part on the faulty assumption that the R3 metal liner was part of the § 510(k)-cleared R3 System. *See id. at 749*.

[18] This is true whether the physician uses the entire device in an off-label manner **[*36]** or, as here, uses a component of the device off-label with components of a separate device. *See, e.g., Hawkins, 2014 U.S. Dist. LEXIS 11779, 2014 WL 346622, at *5* (rejecting the argument that a component of a PMA-approved device was not subject to federal requirements when used without the other component of the device, as use of the one component without the other was "simply an off-label use of the device"); *Houston v. Medtronic, Inc. (Houston I), 957 F. Supp. 2d 1166, 1176 (C.D. Cal. 2013)* (same).

[19] Plaintiffs argue that even if off-label use of a device does not render § 360k(a) inapplicable when such use was the result of a decision by a physician in which the manufacturer played no part, a different rule applies when the manufacturer actively promotes the off-label use. Citing ***Ramirez v. Medtronic, Inc., supra***, Plaintiffs urge the Court to hold Defendants forfeited the protections of § 360k(a) by promoting the R3 metal liner for use off-label with the R3 System. In *Ramirez*, the court recognized a limited exception to § 360k(a) for state-law

claims based on off-label promotion. The court distinguished such claims from claims based simply on off-label *use* on the ground that the manufacturer's promotion of an off-label use violates federal law and creates a new intended use of the device for which FDA approval is required. *See* ***961 F. Supp. 2d at 990*** (citing *21 C.F.R. § 814.39*, which requires **[*37]** a manufacturer to submit a PMA supplement to introduce new indications for use of a PMA-approved device). The court observed that allowing the manufacturer to enjoy the protections of *§ 360k(a)* in these circumstances would not serve the statute's purpose to avoid having a state body "arrive at a determination regarding a device's safety that conflicts with the conclusion the FDA made after the rigorous PMA process." *See* ***id. at 991***. The court concluded that absent FDA approval of the new intended use created by the manufacturer's off-label promotion, there "[wa]s nothing to preempt state law requirements." *Id. at 993*.

As an initial matter, because the holding in *Ramirez* is limited to claims based on off-label promotion, the case has no application to most of Plaintiffs' claims, which are not specifically based on allegations that Defendants promoted the R3 metal liner for off-label use. Off-label promotion is part of both Plaintiffs' fraud claim and their negligence claim based on violations of federal law, but, even under *Ramirez*, *§ 360k(a)* remains applicable to the remaining claims in Plaintiffs' Second Amended Complaint. As S&N notes, moreover, the *Ramirez* decision has been widely criticized by other district courts reviewing **[*38]** allegations of off-label promotion of PMA-approved devices. *See, e.g., Beavers-Gabriel v. Medtronic, Inc., 15 F. Supp. 3d 1021, 1035 (D. Haw. 2014)* (noting "*Ramirez* has been rejected—for good reason—by numerous courts"). In *Houston v. Medtronic, Inc*. (*Houston II*), for example, the court rejected *Ramirez*'s holding that *§ 360k(a)* does not apply when a manufacturer engages in off-label promotion as inconsistent with the text of the statute, under which preemption turns on whether there are federal requirements applicable to the device, not to a particular use of the device. *No. 13-1679, 2014 U.S. Dist. LEXIS 50613, 2014 WL 1364455, at *5 (C.D. Cal. Apr. 2, 2014)* (noting "[i]f *§ 360k(a)* does not distinguish between uses of a device, it surely does not distinguish between whether a particular use of a device was promoted by the manufacturer"). The court also found *Ramirez* was inconsistent with "the scope of federal requirements imposed on Class III devices," noting manufacturers of PMA-approved devices are required to report to the FDA information reasonably suggesting a device may have caused or contributed to a death or serious injury, and are prohibited from "making changes in 'design specifications, manufacturing processes, [or the] labeling' of devices without FDA approval, regardless of use." *Id*. (quoting *Riegel, 552 U.S. at 319*). While the court agreed with *Ramirez* that off-label promotion **[*39]** violates federal law, the court viewed the federal prohibition as a possible basis for a parallel claim, rather than a wholesale exemption from preemption. *See 2014 U.S. Dist. LEXIS 50613, [WL] at *8*. This Court agrees a manufacturer's promotion of off-label uses of a PMA-approved device does not affect whether the device is subject to federal requirements for purposes of *§ 360k(a)*. Rather, consistent with *Houston*, the Court will consider Plaintiffs' allegations regarding off-label use as the basis for a potentially nonpreempted parallel claim.

Having concluded that the FDA's approval of the PMA supplement for the R3 Metal on Metal Cup imposed federal requirements on the R3 metal liner for purposes of *§ 360k(a)*, the Court must next determine whether Plaintiffs' state-law claims impose requirements "with respect to" the liner that are "different from, or in addition to" the federal requirements. In their Second Amended Complaint, Plaintiffs assert variations of the same seven counts included in their First Amended Complaint: (1) negligence/negligence per se (Count I), (2) negligence based on violations of FDA regulations and FDCA provisions (Count II), (3) strict products liability (Count III), (4) breach of express warranty (Count IV), (5) **[*40]** breach of implied warranties of merchantability (Count V),[20] (6) fraud (Count VI), and (7) loss of consortium (Count VII). Plaintiffs acknowledge Count II represents their attempt "to articulate parallel claims," i.e., state-law claims based on violations of federal law, "should the Court find preemption." Oral Arg. Tr. 80, July 16, 2014. S&N argues the Complaint should be dismissed in its entirety because Counts I and III-VI are preempted,[21] Count II fails to state a plausible parallel claim for violations of state common-law duties that parallel the federal requirements applicable to the R3 metal liner, and Count VII is derivative of, and thus cannot survive dismissal of, the remaining counts.

The claims in Plaintiffs' Second Amended Complaint are broad-ranging and extremely general. For their negligence claim, Plaintiffs allege Defendants failed to exercise ordinary **[*41]** care in "the designing, researching, manufacturing, marketing, labeling, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the R3 Acetabular System, and components such as the R3 metal liner that foreseeably would be used with it." Second Am. Compl. ¶ 119. Plaintiffs' strict liability claim alleges "[t]he R3 Acetabular System, both with and

[20] The Second Amended Complaint mistakenly refers to the breach of implied warranties claim, which follows Count IV, as Count VI.

[21] As to Count IV, S&N also argues that insofar as the MDA does not preempt claims for breach of express warranty claims, Plaintiffs have failed to plead a plausible express warranty claim in this case.

without components such as the R3 metal liner that foreseeably would be used with it," was "defective in design or formulation," *id*. ¶ 141, and that "[t]he R3 Acetabular System and components such as the R3 metal liner that foreseeably would be used with it" were "manufactured defectively" and were defective due to inadequate warnings, instructions, testing, and/or post-marketing surveillance, *see id*. ¶¶ 149, 153-55. The breach of implied warranty claim rests on allegations that Defendants breached implied warranties that "the R3 Acetabular System and components such as the R3 metal liner that foreseeably would be used with it" were "safe and of merchantable quality, and fit for the ordinary purpose for which said product[s] w[ere] to be used." *See id*. ¶¶ 173, 178.

All of these claims unquestionably relate to the safety **[*42]** of the R3 System and the R3 metal liner when used together, and insofar as the claims are directed to the PMA-approved liner, they are expressly preempted by *§ 360k(a)*. *See Riegel, 552 U.S. at 320, 324-25* (holding *§ 360k(a)* preempted state-law claims of "strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale" of a PMA-approved device). Although Plaintiffs' claims also purport to challenge the safety of the § 510(k)-cleared R3 System, the body of the Second Amended Complaint reveals that the liner is at the heart of each of Plaintiffs' claims. The Second Amended Complaint identifies the metal-on-metal articulation of the R3 metal liner and the femoral head components of the R3 System as the source of Mr. Shuker's injuries, alleging this articulation was "prone to wearing down and releasing metal debris into the body of the user[,] causing adverse health effects," and also alleging Dr. Terefenko determined Mr. Shuker's pain "was caused by metal sensitivity due to the degeneration of the metal on metal articulation." Second Am. Compl. ¶¶ 98, 111; *see also id*. ¶¶ 95, 105, 120(t), 120(x), 183. Moreover, the Second Amended Complaint identifies the metal liner—not **[*43]** the femoral components—as the source of the problem, alleging Defendants ultimately withdrew the liner "within the R3 Acetabular System" because it was not performing satisfactorily within that System,[22] *see* Second Am. Compl. ¶ 100, and that regulatory authorities in the United Kingdom advised surgeons to stop using the metal liner because of its unacceptably high revision rate, *see id*. ¶ 102. Dr. Terefenko's operative report for Mr. Shuker's July 2011 revision surgery confirms that Dr. Terefenko identified the metal liner as the "primary generator of the metallic debris." Pls.' Summ. J. Ex. D at 4.

The only factual allegation in the Second Amended Complaint pertaining to the R3 System, as opposed to the liner, concerns the adequacy of the warnings accompanying the System. Plaintiffs allege that while the literature accompanying the BHR System warned surgeons that "when performing a hip resurfacing procedure, the R3 acetabular shell must be used only with an R3 metal liner and the BHR femoral head," Defendants "failed to provide the reverse admonition for the R3 Acetabular System; namely, when performing a hip replacement with the R3 Acetabular System's femoral components, do not mate them with the R3 metal liner." *Id*. ¶ 40 (emphasis omitted); *see also id*. ¶ 129(q), (s) (noting the individual components of the R3 System "do not provide warnings to not use these device components with the R3 metal liner leading users to believe it is safe"). A warning against using the R3 metal liner with the R3 System in a hip replacement procedure is undoubtedly a warning that "relates to the safety or effectiveness" of the liner, regardless of whether the warning **[*45]** accompanies the liner or another component. Allowing Plaintiffs to pursue a claim that the components of the R3 System should have included such a warning would thus effectively impose a state-law requirement "with respect to" the liner that is "different from, or in addition to," the warnings the FDA required. The Court therefore concludes such a claim is no different, for preemption purposes, than a claim challenging the warnings accompanying the liner itself. Because the undisputed facts show Plaintiffs' negligence, strict liability, and breach of implied warranty claims are preempted, judgment will be entered for S&N as to those claims (Counts I, III, and V). *See Simon, 18 F. Supp. 3d at 428-429* (holding strict liability, negligence, and breach of implied warranty claims were preempted by *§ 360k(a)* where the plaintiff

[22] It is not clear whether the recall covered the liner when used within the PMA-approved BHR System. *See* Pls.' Summ. J. Ex. B (FDA's subpoena response characterizing the June 2012 withdrawal of "metal liners of the R3 acetabular system" as "a recall for components sold outside the US," and stating "[t]here was never a US recall from Smith and Nephew in June 2012); S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. C (stating, as part of a S&N "Information and FAQs for Health Care Professionals," that BHR hip implants are not affected by the recall of the R3 metal liner, but also suggesting that, following **[*44]** the recall, "[s]urgeons who had been using a BHR femoral component with an R3 metal liner can immediately switch to the BHR acetabular component").

alleged her injuries "were caused by the 'metal-on-metal' interaction between the metal liner component and the R3 Acetabular System's femoral head component," such that the gravamen of the plaintiff's complaint was "that her injuries were caused by the [PMA-approved] metal liner"); *cf.* Bertini, 8 F. Supp. 3d at 256-57 (holding a claim based on S&N's failure to warn that the R3 System's locking mechanism would not properly secure an R3 **[*46]** metal liner to the R3 shell was preempted because the "interaction between the R3 metal liner and the R3 locking mechanism ma[de] it impossible for plaintiffs to plead sufficient facts showing that the R3 locking mechanism, on its own, caused their injuries").

HN12[↑] The MDA does not preempt claims for breach of express warranty as express warranties "do not independently arise by operation of state law" and claims for breach of such warranties thus "do[] not involve . . . state 'requirement[s].'" Bentzley v. Medtronic, Inc., 827 F. Supp. 2d 443, 454-55 (E.D. Pa. 2011); *accord* Starks v. Coloplast Corp., No. 13-3872, 2014 U.S. Dist. LEXIS 19611, 2014 WL 617130, at *6 (E.D. Pa. Feb. 18, 2014). HN13[↑] Under Pennsylvania law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." 13 Pa. Cons. Stat. § 2313. Because express warranties are specifically negotiated, "to create an express warranty, the seller must expressly communicate the terms of the warranty to the buyer in such a manner that the buyer understands those terms and accepts them." Goodman v. PPG Indus., Inc., 2004 PA Super 151, 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004), *aff'd*, 584 Pa. 537, 885 A.2d 982 (Pa. 2005).

The breach of express warranty claim in Plaintiffs' Second Amended Complaint is based on the wholly conclusory allegations that Defendants "expressly warranted that the R3 Acetabular System and components such as **[*47]** the R3 metal liner that foreseeably would be used with it w[ere] safe and/or well accepted by users," Second Am. Compl. ¶ 162, and "w[ere] safe and fit for use for the purposes intended, . . . w[ere] of merchantable quality, . . . did not produce any dangerous side effects, and . . . w[ere] adequately tested and fit for [their] intended use," *id.* ¶ 167. S&N argues this claim is inadequately pleaded. The Court agrees. The Second Amended Complaint does not identify the source of the warranty (i.e., whether it was made in a publication, package insert, or advertising) and does not say how Mr. Shuker or Dr. Terefenko became aware of it, much less how it became the basis of the bargain between Mr. Shuker and S&N. Nor have Plaintiffs adequately described the content of the warranty, beyond agreeing at oral argument they were *not* claiming Defendants expressly warranted that the R3 System was safe for use in conjunction with the metal liner. *See* Oral Arg. Tr. 74. Because Plaintiffs have failed to plead facts supporting a plausible inference that an express warranty was created, their claim for breach of express warranty (Count IV) will be dismissed with prejudice pursuant to Rule 12(b)(6). *See* Starks, 2014 U.S. Dist. LEXIS 19611, 2014 WL 617130, at *7 (dismissing a breach **[*48]** of express warranty claim where the plaintiff failed to "plead any details regarding the content of any express warranty, how it was made, that it became the basis of the bargain, or that it was directed to [plaintiff]"); Dougherty v. C.R. Bard, Inc., No. 11-6048, 2012 U.S. Dist. LEXIS 100374, 2012 WL 2940727, at *9 n.15 (E.D. Pa. July 28, 2012) (holding to plead a plausible breach of express warranty claim, a plaintiff must allege such facts as "the specific source of the alleged warranty . . . and the specific statements made"); Kester v. Zimmer Holdings, Inc., No. 10-523, 2010 U.S. Dist. LEXIS 59869, 2010 WL 2696467, at *9-10 (W.D. Pa. June 16, 2010) (dismissing a breach of express warranty claim based on the allegation that defendants "expressly warranted that [their devices] were safe and well accepted by users").

Plaintiffs' remaining claims—their claim for negligence based on violations of FDA regulations and FDCA provisions and their fraud claim—are premised on Defendants' alleged violations of federal law.[23] As noted, HN14[↑] because § 360k(a) preempts only those state requirements with respect to a device that are "different from, or in addition to," the federal requirements applicable to the device, the statute "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations," as "the state duties in such a case 'parallel,' rather than add to, federal requirements." Riegel, 552 U.S. at 330; *see also* Lohr, 518 U.S. at 495. While a parallel **[*49]**

[23] As discussed below, Plaintiffs' fraud claim is based on allegations that Defendants promoted the sale of the R3 System in combination with the R3 metal liner without disclosing the known risks associated with the combined use of the products. *See* Second Am. Compl. ¶¶ 183-85. Because these allegations relate to off-label promotion, the Court construes Plaintiffs' fraud claim one based on Defendants' violation of federal law.

claim must be based on the manufacturer's violation of federal law in order to avoid express preemption, the claim must not arise "*solely* from the violation of FDCA requirements," lest it be impliedly preempted as an attempt to privately enforce the FDCA. *See* Buckman, 531 U.S. at 352-53 (emphasis added). The claim must still be grounded in a violation of state-law duty. *See id*. To plead a parallel claim successfully, a plaintiff's allegations must meet the plausibility standard articulated by the Supreme Court in *Iqbal* and *Twombly*. *See* Bass v. Stryker Corp., 669 F.3d 501, 509 (5th Cir. 2012); Bausch, 630 F.3d at 558. The plaintiff must plead that the manufacturer failed to comply with federal law and that this failure caused his injury. *See* Bass, 669 F.3d at 512.

In Count II of their Second Amended Complaint, Plaintiffs allege Defendants were negligent in that they breached their duty "to **[*50]** comply with the [FDCA] and the regulations promulgated pursuant to the Act" by violating a host of statutory and regulatory provisions. *See* Second Am. Compl. ¶¶ 128-29. Although defendants devote twenty pages—approximately one-third of the Second Amended Complaint—to cataloging these alleged violations, they offer no legal support for, or explanation of, most of the theories they seek to advance in their briefing of S&N's motion for summary judgment or their own motion for leave to amend. As a result, the Court is left to parse a lengthy laundry list of FDCA provisions and FDA regulations.

The main parallel claim Plaintiffs seek to pursue is a claim based on Defendants' promotion of the R3 metal liner for use off-label with the R3 System. *See* Pls.' Summ. J. Opp'n 15-16; Pls.' Mot. for Leave to *Amend* 10. A number of the allegations in Count II are directed to off-label promotion. For example, Plaintiffs allege Defendants were negligent in "[p]roviding false and misleading advertising" regarding the R3 metal liner by referring to the liner as "optional" for the R3 system, thereby "creating the false impression that the R3 [A]cetabular [S]ystem had a metal liner component that could be used safely in hip replacements," in violation **[*51]** of *21 U.S.C. §§ 352(q)* and *331(a)*. Second Am. Compl. ¶ 129(r). Plaintiffs further allege Defendants were negligent in providing false and misleading information regarding unapproved uses of the R3 metal liner in hip replacement procedures, in violation of *21 C.F.R. §§ 99.101* and *99.103*. *See id*. ¶ 129(x)-(ee); *see also id*. ¶ 129(gg). Off-label promotion is also the subject of Plaintiffs' fraud claim, which alleges Defendants received notice, "through studies, reports, and/or experience," that the metal-on-metal articulation of the R3 metal liner and the femoral components of the R3 System was capable of producing "deleterious volumes of metallic debris," but nevertheless promoted the sale of the R3 System in combination with the R3 metal liner without disclosing the risks associated with the combined use of the products. *See id*. ¶¶ 183-85.

As S&N acknowledges, and as numerous courts have recognized, off-label promotion can be a basis for a nonpreempted parallel claim in some circumstances, as federal law has generally been interpreted to prohibit off-label promotion, at least when it is false and misleading. *See* Oral Arg. Tr. 44, 48 (agreeing that "in appropriate circumstances an off-label promotion claim could go forward"); *see also, **[*52]** e.g.,* Carson v. DePuy Spine, Inc., 365 F. App'x 812, 815 (9th Cir. 2010) (holding "the marketing and promotion of a Class III device for an unapproved use violates Section 331 of the FDCA"); Schouest v. Medtronic, Inc., 13 F. Supp. 3d 692, 701-02 (S.D. Tex. 2014) (concluding that although federal law "does not expressly . . . ban[] off-label promotion," it does bar such promotion "when it is false or misleading"); *cf.* In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 239-40 (3d Cir. 2012) (noting the FDCA "generally prohibits manufacturers from marketing, advertising, or otherwise promoting drugs for . . . unapproved or 'off-label' uses"). The precise contours of such a claim are not clear, as the law in this area is continuing to evolve.[24]

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[24] Many courts have held that state-law claims based on a manufacturer's affirmative misrepresentations in the course of promoting a device for off-label use—e.g., claims for fraud, breach of express warranty, and negligent misrepresentation—are neither expressly nor impliedly preempted. *See, e.g.,* Schouest, 13 F. Supp. 3d at 703-05; Houston I, 957 F. Supp. 2d at 1179-81. As the court in *Schouest* explained, such claims are not expressly preempted because "making false or misleading statements about medical devices is prohibited by federal law," and are not impliedly preempted because they are rooted in "independent state law duties that [the manufacturer] allegedly violated after the initial PMA process." 13 F. Supp. 3d at 703-05. While some courts have suggested claims based **[*53]** on omissions in the course of off-label promotion may also escape preemption, *see, e.g.,* Eidson v. Medtronic, Inc. (Eidson II), 40 F. Supp. 3d 1202, 1228 (N.D. Cal. 2014) (holding fraudulent and negligent misrepresentation claims challenging, inter alia, a manufacturer's omission of information regarding known dangers associated with the off-label use it was promoting were not preempted); Riley, 625 F. Supp. 2d at 783-84

The Court need not determine the bounds of a permissible parallel claim based on off-label promotion, however, as Plaintiffs have not pleaded facts supporting a plausible inference that Defendants engaged in off-label promotion of the R3 metal liner that influenced the selection of the liner for use in Mr. Shuker's surgery. While Plaintiffs allege Defendants promoted **[*54]** and advertised the liner as "optional" for use with the R3 System, the only instance of such promotion identified in the Second Amended Complaint is the February 2009 press release in which S&N announced the introduction of "an optional 'metal liner' for the R3 Acetabular System."[25] Second Am. Compl. ¶ 91; *see also* S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. A (press release). It is not clear whether the press release amounts to off-label promotion. While the press release describes the metal liner as an "option" for the "R3 Acetabular System, an advanced multi-bearing acetabular cup system used in hip replacement and resurfacing procedures," it discloses that the FDA approved the metal liner "for use with the BIRMINGHAM HIP™ Resurfacing . . . System." S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. A. The press release does not represent the metal liner was approved for use in hip replacement procedures, but states, with respect to hip replacements, that "[s]ince March 2008, the R3 system has been fitted with cross-linked polyethylene (XLPE) liners for use in total hip replacement cases, and Smith & Nephew this week received FDA approval of its ceramic liner option." *Id*. Nevertheless, **[*55]** even assuming the press release is misleading in referring to the liner as an option for use with the R3 System, which, in the United States, "is a total hip replacement system component," Pls.' Summ. J. Ex. B, the Second Amended Complaint alleges no facts suggesting Dr. Terefenko or Mr. Shuker were even aware of the press release, much less that the representations in the press release led to Dr. Terefenko's use of the metal liner in Mr. Shuker's surgery. Although Plaintiffs cite Dr. Terefenko's surgical notes as "allud[ing] to" Defendants' promotional efforts, the surgical notes indicate only that Dr. Terefenko and Mr. Shuker agreed "a metal-metal articulation [wa]s appropriate" for Mr. Shuker, in light of his "body habitus and his activity level." Second Am. Compl. ¶ 55. The notes say nothing about how Dr. Terefenko came to select *Smith & Nephew* components for Mr. Shuker's surgery. Further, insofar as Plaintiffs seek to pursue a fraud claim based on off-label promotion, they have not pleaded this claim within anywhere near the particularity required by Federal Rule of Civil Procedure 9(b). *See* Fed. R. Civ. P. 9(b) (**HN15**[] "In alleging fraud . . . , a party must state with particularity the circumstances constituting fraud."); Houston I, 957 F. Supp. 2d at 1180 (dismissing fraud claims based **[*56]** on off-label promotion with leave to amend where the plaintiff failed to allege, inter alia, "to whom [the allegedly fraudulent misrepresentations] were made[,] . . . which parts of the misrepresentations were misleading, and *why* they [we]re false"). Accordingly, Plaintiff's fraud claim (Count VI) and Count II, insofar as it is based on off-label promotion, will be dismissed. The Court will, however, grant Plaintiffs leave to amend as to these claims.

Plaintiffs also seek to pursue a parallel claim based on Defendants' failure to report adverse events associated

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(suggesting a claim that, while engaging in off-label promotion, a manufacturer failed to warn about the off-label use it was promoting might not be preempted), other courts have disagreed, *see, e.g.*, Schouest, 13 F. Supp. 3d at 705 (holding a negligent misrepresentation claim was expressly preempted insofar as it was premised on the manufacturer's failure to disclose that the promoted off-label use of the device could cause injuries); Hawkins, 2014 U.S. Dist. LEXIS 11779, 2014 WL 346622, at *15 (holding a claim for failure to provide adequate warnings during off-label promotion was expressly preempted).

[25] Plaintiffs also allege Defendants engaged in off-label promotion by publishing an R3 Acetabular System brochure that describes the surgical technique for inserting the metal liner with the R3 Acetabular System, even though the FDA never approved the metal liner for use with the R3 System. *See* Second Am. Compl. ¶¶ 60-66. The brochure itself—which is included in Plaintiffs' summary judgment exhibits—belies these allegations. The cover page to the brochure bears the heading, "Poly up to 44 mm heads," a reference to the poly liner that received § 510(k) clearance as part of the R3 System, and the brochure goes on to describe the procedure for inserting only a poly (or XLPE) liner into the R3 acetabular shell. *See* Pls.' Summ. J. Ex. A at 13167-90. Plaintiffs **[*57]** seize on the fact that the page of the brochure focused on "R3 acetabular liner insertion" includes a paragraph setting forth certain procedures to be followed "[b]efore inserting the *R3 acetabular liner*," then specifies further instructions "[f]or *XLPE liner insertion*," arguing the reference to the "R3 acetabular liner" constitutes off-label promotion of the R3 *metal* liner for use with the R3 System. *See id*. at 13175 (emphasis added). This interpretation is not plausible. While it is possible the paragraph regarding the procedures to be followed before inserting the R3 acetabular liner includes information generic to all liners of the R3 System, the brochure nowhere mentions the R3 metal liner, and nothing in it suggests it is directed to anything other than the technique for inserting the R3 shell and poly liner. That the brochure is directed to the poly liner is underscored by the six pages it devotes to cataloging S&N's various poly liner options. *See id*. at 13176-77, 13179-80, 13182-83.

with use of the R3 metal liner in hip replacement procedures to the FDA, in violation of 21 U.S.C. § 360i, 21 C.F.R. § 803.50, and other FDA regulations. *See* Second Am. Compl. **[*58]** ¶ 129(f), (m)-(p), (jj). The Fifth and Ninth Circuits have held that state-law failure-to-warn claims based on similar allegations are not preempted. In Hughes v. Boston Scientific Corp., 631 F.3d 762, 770-71 (5th Cir. 2011), the Fifth Circuit held a claim that a device manufacturer violated its duty to warn under Mississippi law by failing to accurately report serious injuries and malfunctions of its device, as required under federal law, was a nonpreempted parallel claim. Likewise, in Stengel v. Medtronic, Inc., 704 F.3d 1224, 1232-33 (9th Cir. 2013) (en banc), the Ninth Circuit held a claim that a device manufacturer breached a duty to use reasonable care under Arizona negligence law by failing to perform its federal-law duty to warn the FDA of adverse events involving its device was not preempted where Arizona tort law "include[d] a cause of action for failure to warn" and "contemplate[d] a warning to a third party such as the FDA." The Eighth Circuit has taken a different view, holding a claim that a device manufacturer "did not timely file adverse event reports, as required by federal regulations," was "an attempt by private parties to enforce the MDA" and was therefore impliedly preempted under *Buckman*. In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1205 (8th Cir. 2010).

S&N argues this claim is inadequately pleaded because Plaintiffs do not specify the adverse events Defendants failed to report and do not allege **[*59]** how the reports would have reached Dr. Terefenko and changed his treatment decision. S&N also argues the claim is factually implausible because Mr. Shuker's surgery occurred only two months after the R3 metal liner was released in the United States, and it is virtually impossible that adverse events could have occurred, been reported to the FDA, and found their way to Dr. Terefenko in sufficient numbers to have affected his treatment decision during this narrow two-month window. As to S&N's factual implausibility argument, it not clear that the February 2009 United States launch date for the R3 metal liner is the appropriate starting point for Defendants' duty to report adverse events. Although the metal liner was not released in the United States until February 2009, it received "approval in Europe for market evaluation in January 2007 and for full launch in December 2007, and it was included on the Australian Register of Therapeutic Goods in January 2007." S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. C. At oral argument, Plaintiffs argued the reportable adverse events were not limited to experience with the R3 metal liner in the United States, noting the recall of the liner was **[*60]** based on "information globally coming back to Smith & Nephew in the UK." Oral Arg. Tr. 82-83. While S&N maintained "the clock started running again" for purposes of the company's reporting obligations when the liner received premarket approval, *see id*. at 97, the FDA granted premarket approval in November 2008, some six months before Mr. Shuker's April 2009 surgery.

The Court agrees, however, that Plaintiffs have failed to plead sufficient facts to render their claim plausible. Even if Plaintiffs need not "specify" the particular adverse events Defendants allegedly failed to report, there must be some factual basis from which it can plausibly be inferred that such events occurred and that Defendants failed to report them during the six-month window in question. The fact that Defendants recalled the R3 metal liner in June 2012 based on data indicating the liner was not performing satisfactorily within the R3 System supports a plausible inference that Defendants became aware of adverse events involving the liner prior to June 2012, but there is nothing in the Second Amended Complaint to suggest that Defendants failed to report such events to the FDA at any point, much less prior to Mr. Shuker's **[*61]** surgery in April 2009. *Cf.* Stengel, 704 F.3d at 1227 (allegations that device manufacturer failed to report adverse events to the FDA included the allegation that FDA sent a warning letter to the manufacturer two years after plaintiff became paralyzed, stating the manufacturer had misbranded its device by concealing known risks). Plaintiffs have likewise failed to plead facts supporting a plausible inference that had the undisclosed adverse events been reported to the FDA during the six-month window in question, information about those events would have reached Dr. Terefenko in time to prevent Mr. Shuker's injuries. Plaintiffs allege only that had Defendants properly reported all adverse events, "Defendants or the FDA would have taken corrective action," *see* Second Am. Compl. ¶ 129(m)-(p), but this is precisely the sort of conclusory allegation the Fifth Circuit found "entirely speculative" in *Hughes*. *See* 631 F.3d at 776 n.12 (rejecting plaintiff's theory that had the manufacturer properly reported all adverse events, the FDA would have taken some regulatory action against the device).[26] For these reasons, Plaintiffs' parallel claim based on Defendants failure to report adverse events to the FDA will be dismissed with prejudice. **[*62]**

[26] Plaintiffs' allegations regarding Defendants' failure to investigate and take appropriate corrective action with respect to complaints and returned components suffer from similar deficiencies. *See* Second Am. Compl. ¶ 129(e), (g).

A number of the allegations in Count II are directed to the labeling for the R3 metal liner and/or the components of the R3 System, which Plaintiffs assert was insufficient to alert physicians and patients to the dangers of using the R3 metal liner with the components of the R3 System in a total hip replacement. *See* Second Am. Compl. ¶ 129(i)-(j), (q), (s)-(v), (hh). Although couched as violations of federal law, these allegations are directed to the FDA-approved labeling for the R3 liner, which Defendants were precluded from changing without prior FDA approval. Any claim based on these allegations is therefore expressly preempted. *See* *Hughes, 631 F.3d at 769* (holding state-law claims that "would question the sufficiency of the FDA-approved labeling, warnings, and instructions for [a PMA-approved medical device] or require [the manufacturer] to have included different warnings, labels, or instructions with the device" were expressly preempted); *In re Medtronic, Inc., 623 F.3d at 1205* (holding claim that a device manufacturer **[*63]** failed to adequately warn consumers of known defects in its device was preempted by *§ 360k(a)* where plaintiffs "did not allege [the manufacturer] modified or failed to include FDA-approved warnings"); *Horn, 376 F.3d at 177 & n.22* (holding a claim "premised on the adequacies of the warnings reviewed and approved by the FDA in its PMA approval order" was preempted). Plaintiffs elsewhere allege Defendants violated *21 C.F.R. § 1.21* by issuing "brochures, inserts and other materials at variance with what the FDA approved," but they provide no explanation of any such deviation. *See* Second Am. Compl. ¶ 129(ii).

The remaining allegations in Count II are difficult to categorize and, in many instances, incomprehensible to the Court. For example, Plaintiffs allege Defendants failed to identify, capture, and/or correct the "component discrepancy," in violation of *21 C.F.R. § 820.80*, but do not explain what this term, which does not appear in the cited regulation, refers to. *See* Second Am. Compl. ¶ 129(c)-(d). It is not clear whether this allegation is directed to a manufacturing defect or some other problem, and insofar as Plaintiffs seek to assert a claim based on a manufacturing defect, it is not clear what facts support the inference that the R3 metal liner **[*64]** implanted in Mr. Shuker was not manufactured in accordance with federal requirements. While the liner was recalled, Plaintiffs do not plead facts suggesting the recall was associated with a manufacturing problem. *See id*. ¶¶ 100-02 (alleging the recall was based on data indicating the metal liner was not performing satisfactorily within the R3 System); *cf.* *Bausch, 630 F.3d at 559* (holding a plaintiff had pleaded a plausible parallel manufacturing defect claim where the complaint alleged the device was implanted in the plaintiff's body six days after the FDA informed the manufacturer that a device component was "adulterated due to manufacturing methods . . . not in conformity with industry and regulatory standards" and where the implanted device was later recalled). The Court likewise concludes any remaining allegations in Count II are insufficient to state a plausible parallel claim.

Having considered S&N's arguments for summary judgment and/or dismissal as to Plaintiffs' Second Amended Complaint, the Court concludes the claims set forth therein are either preempted (Counts I, III, and V, and Count II insofar as it challenges the FDA-approved labeling for the PMA-approved R3 metal liner) or fail to state a **[*65]** claim upon which relief can be granted (Counts IV and VI, and the balance of Count II). Accordingly, the Second Amended Complaint will be dismissed.[27] The Court will, however, grant Plaintiffs leave to amend as to their claims based on off-label promotion.

An appropriate order follows.

BY THE COURT:

/s/ Juan R. Sánchez

Juan R. Sánchez, J.

ORDER

AND NOW, this 31st day of March, 2015, for the reasons set forth in the accompanying Memorandum, it is ORDERED Plaintiffs' Motion for Leave to File Second Amended Complaint Based on Results of Court-Ordered Discovery (Document 66) is GRANTED. The proposed Second Amended Complaint attached as Exhibit E to Plaintiffs' Motion shall be deemed filed.

It is further ORDERED Defendant Smith & Nephew, Inc.'s Motion for Summary Judgment (Document 59) is GRANTED as follows:

- Judgment is entered in favor of Smith & Nephew, Inc. as to Counts I, III, and V of the Second Amended Complaint on the basis that the claims set forth in those Counts are expressly preempted under *21 U.S.C. § 360k(a)*.

[27] The dismissal also extends to Count VII, Plaintiffs' claim for loss of consortium, which is derivative of their other claims.

• Counts II, IV, VI, and VII of the Second Amended Complaint are dismissed **[*66]** pursuant to *Federal Rules of Civil Procedure 12(b)(6)* and/or *9(b)*. Insofar as Counts II and VI are based on off-label promotion, those claims are dismissed without prejudice to Plaintiffs' right to file a further amended complaint that corrects the pleading deficiencies identified in the accompanying Memorandum. Count VII is also dismissed without prejudice. Plaintiffs shall have until April 30, 2015, to file a further amended complaint. Count IV and the balance of Count II are dismissed with prejudice.

BY THE COURT:

/s/ Juan R. Sánchez

Juan R. Sánchez, J.

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Simchon v. Highgate Hotels, LP

United States District Court for the Middle District of Pennsylvania

November 7, 2016, Filed

3:15-CV-01434

Reporter
2016 U.S. Dist. LEXIS 154295 *; 2016 WL 6595918

ERICA BLOOM SIMCHON, ISSAC SIMCHON, NICHOLAS PADULA, ALIZA SEIBERT, and ANDREW SIEBERT, on behalf of themselves and others similarly situated, Plaintiffs, v. HIGHGATE HOTELS, LP, COVE HAVEN, INC., and STARWOOD HOTELS & RESORTS WORLDWIDE, INC., Defendants.

Prior History: *Simchon v. Highgate Hotels, L.P., 2016 U.S. Dist. LEXIS 125039 (M.D. Pa., Sept. 13, 2016)*

Core Terms

Recommendation, Plaintiffs', residents, unjust enrichment

Counsel: **[*1]** For Erica Bloom Simchon, on behalf of themselves and others similarly siutated, Isaac Simchon, on behalf of themselves and others similarly siutated, Nicholas Padula, on behalf of themselves and others similarly siutated, Plaintiffs: Matthew J Blit, LEAD ATTORNEY, Levine & Blit, PLLC, New York, NY; Russell S Moriarty, LEVINE & BLIT, PLL, NEW YORK, NY.

For Highgate Hotels, LP, Cove Haven, Inc., Defendants: Donald D. Gamburg, Ogletree Deakins Nash Smoak & Stewart, P.C., Philadelphia, PA; Evan B. Citron, Ogletree, Deakins, Nash, Smoak & Stewart, New York, NY; William F Birchfield, Ogletree, Deakins, Nash, Smoak & Stewart, PC, New York, NY.

For Starwood Hotels & Resorts Worldwide, Inc., Defendant: Amanda E Colvin, Daniel M O'Keefe, Bryan Cave LLP, St. Louis, MO; David E. Heisler, Cipriani & Werner, P.C., Scranton, PA.

Judges: Robert D. Mariani, United States District Judge.

Opinion by: Robert D. Mariani

Opinion

ORDER

The background of this Order is as follows: on September 13, 2016, Magistrate Judge Carlson issued a Report and Recommendation in which he recommends that this Court grant in part and deny in part the Defendants' Motions to Dismiss. (Doc. 61). Defendants Highgate Hotels, L.P., Cove Haven, Inc. and Starwood **[*2]** Hotels & Resorts Worldwide, Inc. have filed Objections to the Report and Recommendation. (Docs. 62, 63).

Defendants Highgate Hotels, L.P, and Cove Haven, Inc. "do not object to the Report overall and specifically do not object to the Report's recommendation that (1) The claims made by the Simchon plaintiffs under *New York General Business Law Section 349* should be DISMISSED as time-barred, and (2) . . . Defendant Highgate may not be held liable for any claims brought by the plaintiffs' which pre-date its acquisition of these properties in 2012." (Doc. 62, at 2). Nevertheless, Defendants Highgate Hotels L.P. and Cove Haven, Inc. "object to those portions of the Report which conclude that the Amended Complaint (1) adequately states civil RICO and common law fraud claims . . . (2) adequately states a claim under Pennsylvania Unfair Trade Practices and Consumer Protection Law . . . (3) sufficiently pleads the substantive elements of a statutory claim under *New York General Business Law Section 349* . . . and (4) states a claim for unjust enrichment." (*Id.* at 2-3).

Defendant Starwood Hotels & Resorts Worldwide, Inc.'s partial objection takes issue with the Magistrate Judge's recommendation that the Court deny Defendant's Motion to Dismiss Plaintiffs' claims under the Pennsylvania **[*3]** Unfair Trade Practices and Consumer

Protection Law. (Doc. 63, at 1-2). Specifically, "Starwood objects to Section II.D of the Report and Recommendation ('The Amended Complaint Adequately States a Claim under Pennsylvania's Unfair Trade Practices and Consumer Protection Law, 73 Pa.C.S. §201-1 (UTPCPL))'" (*Id.*). According to Starwood, "because the Simchon Plaintiffs and the Seibert Plaintiffs were not Pennsylvania residents, and the UTPCPL only provides redress for plaintiffs who reside in Pennsylvania," those claims must be dismissed. (*Id.* at 2). Moreover, Starwood maintains that "case law in Pennsylvania, as well as the underlying purpose of consumer protection law generally, support dismissal of the UTPCPL claims for Plaintiffs Simchons and Plaintiffs Seiberts, who are not Pennsylvania residents, and all non-Pennsylvania putative class members. Thus, the District Court should reject Section II.D of the Report and Recommendation." (*Id.*).

AND NOW, THIS _DAY OF NOVEMBER, 2016, upon *de novo* consideration of Magistrate Judge Carlson's Report and Recommendation, (Doc. 61), **IT IS HEREBY ORDERED THAT**:

1. Defendants Highgate Hotels, L.P. and Cove Haven, Inc.'s Objections, (Doc. 62), are **OVERRULED IN PART AND SUSTAINED** **[*4]** **IN PART**. Specifically, the Court disagrees with the Magistrate Judge's conclusion that the economic loss doctrine does not bar Plaintiffs claims for common law fraud and under the UTPCPL. Although the Pennsylvania Supreme Court has yet to address this issue, the Third Circuit has, and concluded that the doctrine bars claims in circumstances similar to those present here. *See* Werwinski v. Ford Motor Co., 286 F.3d 661 (3d Cir. 2002); *see also* Sunshine v. Reassure Am. Life Ins, Co., 515 F. App'x 140 (3d Cir. 2013). "[W]hen the alleged deceptive conduct is clearly interwoven with the contract, and the plaintiff seeks damages that flow from the contract, a UPTCPL claim cannot be brought." *Fleisher v. Fiber Composites, LLC, Civil Action No. 12-1326, 2012 U.S. Dist. LEXIS 157343, 2012 WL 5381381, at *9 (E.D. Pa. Nov. 2, 2012)*. The Court thus agrees with Defendants that "the economic loss doctrine bars Plaintiffs' UTPCPL [claim] because (1) the parties entered into contracts to reserve Hotel rooms; (2) the allegedly deceptive conduct is interwoven with those contracts; and (3) Plaintiffs seek damages flowing from those contracts." (Doc. 62, at 11). For similar reasons, the Court concludes that Plaintiffs' common law fraud claims must be also dismissed. *See* Werwinski, 286 F.3d at 681. In addition, the Court agrees with the Defendants, that because the relationship between the parties is governed by contract, Plaintiffs' unjust enrichment claims must be also dismissed. *See* Rahemtulla v. Hassam, 539 F. Supp. 2d 755, 780 (M.D. Pa. 2008) ("It is **[*5]** well settled, however, that the doctrine of unjust enrichment is inapplicable when the relationship between the parties is founded upon written agreements, no matter how harsh the provisions of such contract may seem in the light of subsequent happenings.") (internal citation and quotation marks omitted). Defendants' Objection will be overruled in all other respects.

2. Defendant Starwood Hotels & Resorts Worldwide, Inc.'s Partial Objection, (Doc. 63), is **OVERRULED IN PART AND SUSTAINED IN PART**. The Court disagrees with Starwood's assertion that Pennsylvania's UTPCPL only applies to Pennsylvania residents. *See* Mikola v. Penn Lyon Homes, Inc., No. 4:CV-07-0612, 2008 U.S. Dist. LEXIS 44201, 2008 WL 2357688, at *3 (M.D. Pa. June 4, 2008) (rejecting argument that UTPCPL applies only to in-state residents and concluding that "declining to provide protection of UTPCPL to individuals who are not residents of the state, but nevertheless engaged in a large transaction entirely within the state, would invite fraud upon non residents engaged in transactions within the state. . . . Therefore, despite the fact that plaintiffs were not residents of Pennsylvania, we nevertheless find that their allegations establish that they were engaged in a transaction within the state and therefore **[*6]** entitled to the protection of the UTPCPL."). Nevertheless, as discussed above, the Court finds that Plaintiffs' UTPCPL claim to be barred by the economic loss doctrine.

3. The Report and Recommendation, (Doc. 61), is **ADOPTED IN PART AND OVERRULED IN PART**.

4. Defendant Starwood's Motion to Dismiss, (Doc. 19), is **GRANTED IN PART AND DENIED IN PART**. Specifically, the claims made by the Simchon Plaintiffs under New York General Business Law Section 349 are **DISMISSED WITH PREJUDICE**. Plaintiffs' common law fraud claim, unjust enrichment claim, and claim under the UTPCPL are **DISMISSED WITH PREJUDICE**. Moreover, Defendant Starwood is entitled to dismissal of any claims against it relating to conduct occurring after 2012. In all other respects,

Defendant Starwood's Motion to Dismiss is **DENIED**.

5. Defendants Highgate Hotels L.P. and Cove Haven Inc.'s Motion to Dismiss, (Doc. 21), is **GRANTED IN PART AND DENIED IN PART**. Specifically, the claims made by the Simchon Plaintiffs under *New York General Business Law Section 349* are **DISMISSED WITH PREJUDICE**. Plaintiffs' common law fraud claim, unjust enrichment claim, and claim under the UTPCPL are **DISMISSED WITH PREJUDICE**. Moreover, Defendant Highgate Hotels L.P. may not be held liable for any claims brought by Plaintiffs which pre-date **[*7]** its acquisition of these properties in 2012. In all other respects, Defendants Highgate Hotels L.P. and Cove Haven Inc.'s Motion to Dismiss is **DENIED**.

/s/ Robert D. Mariani

Robert D. Mariani

United States District Judge

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Victaulic Co. v. Innoveer Solutions

Common Pleas Court of Northampton County, Pennsylvania, Civil Division

May 7, 2009, Decided; May 7, 2009, Filed

NO. C-0048-CV-2009-0197

Reporter
2009 Pa. Dist. & Cnty. Dec. LEXIS 487 *

VICTAULIC COMPANY, Plaintiff v. INNOVEER SOLUTIONS, INC., Defendant.

Core Terms

preliminary objection, breach of contract claim, good faith, unjust enrichment, fair dealing, duplicative, breach of fiduciary duty, cause of action, parties, legal insufficiency, breach of duty, breach of contract, argues, contends, stricken, insurer

Opinion

[*1] STATEMENT OF REASONS

Statement of Facts

Presently before the Court are the Preliminary Objections of Defendant to Plaintiffs Complaint. The Complaint was filed on January 9, 2009 by, Plaintiff victaulic Company ("Plaintiff), alleging claims of breach of contract, unjust enrichment, breach of express warranty, breach of duty of good faith and fair dealing and breach of fiduciary duty against Defendant Innoveer Solutions, Inc. ("Defendant") in connection with a Master Consulting Agreement ("Agreement") between the parties whereby Defendant was to design, develop and install an upgrade to a software system utilized by Plaintiff, and train Plaintiffs staff on the use of the new system.

Plaintiff filed a Complaint on January 9, 2009, which alleges that the software Invoveer designed and installed was riddled with serious flaws that impaired its functionality and resulted in losses of data and productivity. The Complaint alleges that such losses were compounded by Inoveer's failure to adequately train Plaintiffs employees on the software as required under the Agreement.

Standard of Law

In ruling upon preliminary objections the court shall accept as true all well-pled material facts within a plaintiffs **[*2]** complaints, and all reasonable inferences deducible therefrom. *D'Elia v. Folino, 933 A.2d 117, 119 (Pa. Super. Ct. 2007)*. On the basis of these accepted facts and inferences, the inquiry of the court is whether or not recovery is possible under the law. Id. In cases where the grant of preliminary objections would necessitate the dismissal of a cause of action, the court should sustain preliminary objections only where it is clear and free from doubt that the law will not permit recovery. *Floors, Inc. v. Altig, 963 A.2d 912, 915 (Pa. Super. Ct. 2009)*. Where any doubt exists as to the sufficiency of a complaint, such doubts shall be resolved in favor of overruling the objection. *Crozer Chester Medical Center v. Dep't. of Labor and Industry Bureau of Worker's Compensation Health Care Svcs. Review Bd., 955 A.2d 1037, 1040 (Pa. Commw. Ct. 2008)*.

Discussion

By the present preliminary objections, Defendant raises several complaints of insufficient specificity and legal insufficiency to the various counts of Plaintiffs Complaint. Defendant's first preliminary objection alleges that Plaintiffs second cause of action, a claim for unjust enrichment, is legally insufficient as a matter of law and should therefore be stricken. As the basis for the objection, Defendant argues that the claim is barred by the existence of a contract between the parties. In support thereof, Defendant cites case law for the proposition that a plaintiff "cannot recover on a claim for unjust enrichment **[*3]** if such claim is based on a breach of a written contract." Honeywell Int'l., Inc. v. Achdiocese of Philadelphia, 2001 WL 1807938 (Pa. Com. Pl. Oct. 24, 2001) (citing *Birchwood Lakes Community Ass'n. v. Comis, 442 A.2d 304, 308 (1982)*. Defendant argues that because there is no dispute

between the parties as to the validity of the underlying contract, the claim for unjust enrichment must fail as a matter of law. Alternatively, Defendant argues that the claim should be stricken as duplicative of Plaintiffs breach of contract claim. As set forth in Defendant's brief, the test for dismissing duplicative claims is to "ask whether the dismissal of a particular claim puts the plaintiff out of court on all theories of recovery against a given defendant for a given loss." *Zikira v. Ass'n. of Thoracic and Cardiovascular Surgeons, P.C., 637 A.2d 1367, 1369 (Pa. Super. Ct. 1994)*.

By a brief contra these preliminary objections, Plaintiff contends that although Pennsylvania law prohibits recovery on a theory of unjust enrichment in the face of a valid contract, both theories may be pled concurrently. Plaintiffs statement of the law in this regard is correct. *Lugo v. Farmer's Pride, Inc., 967 A.2d 963, 970 (Pa. Super. Ct. January 15, 2009)*. While it is true that if in fact there is no dispute between the parties as to the validity of the underlying contract, Plaintiff would be precluded from recovering on theories of both unjust enrichment and breach of contract, [1] the mere fact of pleading both theories concurrently alone is insufficient to warrant **[*4]** that the Plaintiffs unjust enrichment claim be stricken. Nor do we find Plaintiffs unjust enrichment claim duplicative of the breach of contract claim. Rather, the claims are mutually exclusive, as the success of the unjust enrichment claim is dependent on the failure of the breach of contract claim. Accordingly, Defendant's first preliminary objection in the form of a motion to dismiss Count II of Plaintiffs Complaint for legal insufficiency pursuant to *Pa.R.Civ.P. 1028(a)(4)* is hereby **OVERRULED.**

Defendant next moves to strike Plaintiffs claim for breach of express warranty for legal insufficiency pursuant to *Pa.R.Civ.P. 1028(a)(4)*, on the basis that the cause of action is duplicative of the breach of contract claim and should therefore be stricken, given that both claims are based on the same contract, alleging a breach arising from the same course of conduct. However, having already determined that a party may plead in the alternative, Defendant's second preliminary objection is hereby **OVERRULED.**

[1] The only issue raised by preliminary objections is the legal sufficiency of a complaint. In ruling on preliminary objections, the Court must limit itself to a review of the complaint and the exhibits attached thereto. *Delinger, Inc. v. Agresta, 714 A.2d 1048, 1050 (Pa. Super. Ct. 1998)*.

Next, Defendant **[*5]** moves for the dismissal of Plaintiffs breach of duty of good faith and fair dealing claim for legal insufficiency pursuant to *Pa.R.Civ.P. 1028(a)(4)* on the basis that the claim is not only duplicative of Plaintiff's breach of contract claim, but also because the Commonwealth does not recognize breach of the duty of good faith and fair dealing as an independent cause of action. McHale v. NuEnergy Group, 2002 WL 321797 (Pa. Com. Pl. 2002); JHE *Inc. v. SEPTA, 2002 WL 1018941 (Pa. Com. Pl. 2002)*; Commw. v. BASF Corp., 2001 WL 1807788 (Pa. Com. Pl. 2001). It is Plaintiff's assertion, however, that the case law cited by Defendant in support of that position is neither binding on this Court, nor dispositive in the present case. Plaintiff urges that the Court should not follow the logic of JHE given that it was decided in reliance on foreign case law. As for BASF, Plaintiff points out that the Court's dismissal of the breach of duty of good faith claim was based on the plaintiffs failure to also plead breach of contract. Plaintiff concedes that the case law on this subject is muddled, but argues that this much is clear; where a party pleads breach of contract, he may also bring a claim for breach of duty of good faith. Here, Plaintiff pled both a breach of contract claim and a good faith and fair dealing claim. Accordingly, it is Plaintiff's assertion that the good faith and **[*6]** fair dealing claim is legally sufficient for purposes of withstanding the present preliminary objection, noting that several courts "have refused to dismiss good faith and fair dealing claims at the pleading stage□" citing a number of Common Pleas and Federal District Court decisions in support of that proposition. However, this Court is not bound by any decision of another Common Pleas Court. *Castle Pre-Cast Superior Walls of Delaware, Inc. v. Strauss-Hammer, 610 A.2d 503, 505 (Pa. Super. Ct. 1992)*. Nor is this Court bound by decisions of the federal courts on issues of state law. *Drelles v. Manufacturer's Life Ins. Co., 881 A.2d 822, 841* (Pa.

Super. Ct. 2005).

Plaintiff is correct in the assertion that Pennsylvania law on the subject has a muddled history. Some case law seems to indicate that a breach of duty of good faith claim may be established as a derivative to an underlying breach of contract claim, while other cases appear to treat a breach of the duty of good faith as subsumed by a breach of contract claim. This Court's review of the current state of the case law of Pennsylvania's appellate courts on this issue shows that the Commonwealth recognizes the duty of good faith and fair dealing as actionable, it is recognized as the

basis for a breach of contract claim, and not as a separate cause of action. Therefore, Defendant's preliminary **[*7]** objection to the claim on the basis of legal insufficiency pursuant to *Pa.R.Civ.P. 1028* is hereby **SUSTAINED,** and the claim is **STRICKEN. See *Ash v. Continental Ins. Co.*, *932 A.2d 877, 883 (Pa. 2007)*; *LSI Title Agency, Inc. v. Evaluations Svcs., Inc., 951 A.2d 384, 392 (Pa. Super. Ct. 2008)*.

Defendant's fourth preliminary objection challenges Plaintiff' s breach of fiduciary duty claims as legally insufficient on the bases that Plaintiff fails to aver that the relationship between the parties supports such a claim, and that the claim is duplicative of Plaintiff's breach of contract claim. A fiduciary relationship exists "whenever one person has reposed a special confidence in another to the extent that the parties do not deal with each other on equal terms, either because of an overmastering dominance on one side, or weakness, dependence or justifiable trust, on the other." *In re Estate of Clark, 359 A.2d 777, 781 (Pa. 1976)*. Defendant contends that the averments in Plaintiff's Complaint are insufficient to make out such a relationship, and that the mere existence of a contractual relationship is not enough to give rise to a fiduciary relationship. *Wisniski v. Brown & Brown Ins. Co. of Pa., 906 A.2d 571, 579 (Pa. Super. Ct. 2006)*. Accordingly, Defendant argues that Plaintiff's claim must fail.

In response, Plaintiff contends that the averments set forth in the Complaint establish that the computer system that was the subject of the underlying contract was highly technical, and **[*8]** therefore necessitated the assistance of a qualified, experienced consultant. Plaintiff further contends that the averments in the Complaint establish that Defendant held themselves out to Plaintiff in that capacity. Based on those representations, Plaintiff avers that it "relied unequivocally" on Defendant's skill and counsel with respect to the system. Thus, Plaintiff argues, the relationship between the parties, although contractually based, amounted to more than a mere arms-length transaction.

Rather, Plaintiff characterizes the relationship as a business association, whereby Defendant was entrusted with substantial control over the subject computer system on behalf of Plaintiff, thereby giving rise to a fiduciary relationship. See *Commw. v. E-Z Parks, Inc., 620 A.2d 712, 717 (Pa. Commw. 1993)*; Sylk v. Bernsten, 2003 WL 1848565 (Pa. Com. Pl. 2003). Upon review of the relevant case law, the Court finds the averments set forth in Plaintiff's Complaint sufficient to sustain a claim for breach of fiduciary duty. As such, Defendant's preliminary objection thereto is hereby **OVERRULED**. However, in so doing, the Court is noting only the fact as pled, the cause of action is sufficient to withstand preliminary objection. Whether the averments are sufficient to sustain the cause of action through the remainder **[*9]** of the litigation remains to be seen.

Finally, Defendant objects to Plaintiffs breach of fiduciary duty claim on the basis of it's duplicativeness of Plaintiff's breach of contract claim. In support thereof, Defendant cites to a case of the Court of Common Pleas in Lackawanna County, which cites to older case law for the proposition that "in Pennsylvania, a breach of fiduciary duty claim against an insurer by an insured is synonymous with a breach of contractual duty of good faith and fair dealing … [a]s such, a breach of fiduciary duty claim is redundant of a breach of contract claim against an insurer." *Decker v. Nationwide Ins. Co., 83 Pa. D.&C.4th 375, 379 (Pa. Com. Pl. 2007)* (internal citations omitted). Defendant cites that case in their brief, omitting all references to the insurer/insured context. The context, however, is critical. It is the context that renders the case inapplicable to the present matter.

Notwithstanding the inapplicability of the aforementioned case law, Defendant still contends that Plaintiffs claim of fiduciary duty stems entirely from an alleged breach of contract, and should therefore be barred as duplicative pursuant to the gist of the action doctrine.

The gist of the action doctrine bars tort claims "(1) arising solely from a contract **[*10]** between the parties, (2) where the duties allegedly breached were created and grounded in the contract itself; (3) where the liability stems from a contract; or (4) where the tort claim essentially duplicates a breach of contract claim or the success of which is wholly dependent upon the terms of a contract." eToll, *Inc. v. Elias/Savion Advertising, Inc., 811 A.2d 10, 19 (Pa. Super. Ct. 2002)* (internal citations omitted). Upon an examination of Plaintiffs Complaint, it is apparent from the averments in support of the fiduciary duty claim, that Plaintiff is claiming duties owing pursuant to the terms of the underlying Agreement and not from any other source or authority. Thus, it is clear to the Court that Plaintiff cannot be awarded recovery on claims for both breach of contract and breach of fiduciary duty. However, it is also true that a party may plead in the alternative, and that all doubts relative to the resolution of preliminary objections

resulting in the dismissal of a cause of action shall be resolved in favor of dismissing the objection. In light of the foregoing, the Court hereby **OVERRULES** Defendant's preliminary objection to Plaintiffs claim for breach of fiduciary duty.

WHEREFORE, we enter the following:

ORDER OF COURT

AND NOW, this 7th day of May **[*11]** 2009, upon consideration of Defendant's Preliminary Objections to Plaintiffs Complaint, the Court hereby **OVERRULES** Defendant's objections to Plaintiffs claims for unjust enrichment, breach of express warranty, and breach of fiduciary duty. However, Defendant's preliminary objection to Plaintiffs claim for breach of duty of good faith and fair dealing is hereby **SUSTAINED,** as set forth more fully in the attached Statement of Reasons.

BY THE COURT:

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WILLIAM F. MORAN, J.
